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on

Animal Import Risk Analysis

Sunday, August 11, 1991
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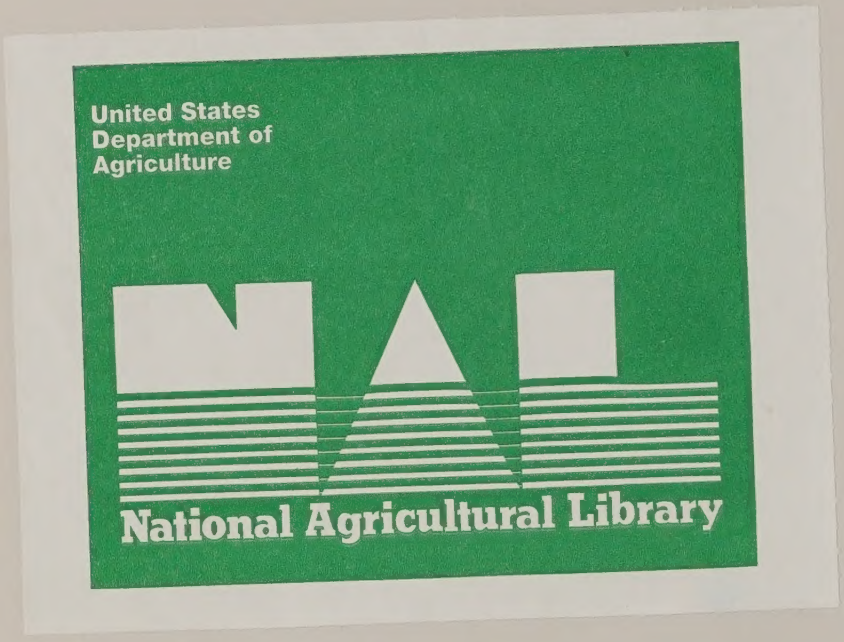
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Introduction

The International Seminar on Animal Import Risk Analysis was held Sunday, August 11, 1991, at Carleton University in Ottawa, Ontario, Canada. This Seminar preceded the meetings for the International Society for Veterinary Epidemiology and Economics, also held at Carleton University, August 12-16, 1991. This International Seminar was sponsored by Planning and Risk Analyis Systems (PRAS) of Policy and Program Development (PPD), Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).

The full-day Seminar featured presentations on import risk analysis from four countries (Australia, Canada, New Zealand, and the United States). In addition, presentations on related issues of standardization and ethics were given. The papers resulting from the Seminar are collected in this Proceedings.

The purpose of this Seminar was to begin an international dialogue on methods and approaches to animal import risk analysis, to share our developing knowledge, and to foster further cooperation. Comments, suggestions, ideas and questions from a broader audience are invited.

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PURPOSE AND GOALS OF THE SEMINAR

N. G. Willis

I am delighted to be able to welcome you, on behalf of Agriculture Canada, to Ottawa, and to this seminar. At this point in time, free trade amongst nations is being sought, both globally and regionally. One has only to look at the extensive negotiations that have taken place to date with the General Agreement on Tariffs and Trade (GATT), and in the North American region with free trade discussions between the United States and Canada, and now including Mexico.

Although the negotiations with GATT have not yet reached a successful consensus, the principles which have been generally accepted are that:

- zero risk is incompatible with active trade;
- restrictions against trade must be supported by scientifically substantiated evidence;
- an acceptable level of risk can be determined through a risk assessment process;
- this process should be transparent; and,
- for clarification of differences between countries, reference can be made to neutral international organizations like the Office International des Epizooties (International Office of Epizootics), OIE.

These trade negotiations have been looking at safely removing tariffs and trade barriers for all goods without the introduction of disease. It therefore becomes essential that national veterinary authorities have a consistent and transparent means of scientifically supporting their import decisions.

A risk analysis system is such a tool and it must, as per its objectives:

- protect the importing country from introducing disease;
- remove time honored animal health barriers to trade that lack a scientific basis.

Of course, it is perfectly clear, that all this operates in a highly complex, multi-dimensional political environment, however, the key to rational and transparent import decision-making must be documented assessment of the risk process.

Other elements which are integral parts of this process are:

- the regionalization concept whereby criteria are developed and internationally accepted for the recognition and control of disease-free zones, and,

- the development of criteria for the assessment of the infrastructure and reliability of the veterinary services of trading countries.

The prospect of the European Economic Community (EEC) becoming a reality in January 1993, brings into challenge the animal health regulations in all EEC countries, and makes it essential to consider the concept of regionalization because of the diverse health status of the member countries. These processes and the elaboration of the various criteria strive to bring science and statistical probabilities together with politics to achieve the essential goals:

- to safeguard national animal health; and
- to promote and facilitate trade.

Risk analysis systems absolutely depend on accurate information of the disease occurrence in exporting countries, and therefore, another essential facet is the willing and reliable revelation of disease data by all participating countries.

At this time, an excellent international system for collecting and distributing such data is operated by the OIE. While readily admitting deficiencies in this system, OIE nevertheless presents the best system available today to serve this purpose, and the best opportunity to build an enhanced information base. Recognizing its pivotal role in this whole process OIE has undertaken to develop guidelines in all these areas.

Canada has accepted the responsibility to lead a multi-country technical group to develop a model risk analysis system which could be accepted by the 115 member countries of OIE. Similarly, model guidelines are being developed for the acceptance and operation of regionalization and for the evaluation of veterinary infrastructure. Once achieved, this will serve as the reference document for dispute settlement as an integral part of the GATT.

Today's presentations include the topics of risk assessment methods, international disease reporting, the implications for world trade, and the responsibility of national veterinarians in disease reporting. The purpose of this seminar is to discuss risk assessment systems for the international trade of animals and animal products, to seek international collaboration in the development of risk analysis systems, and to identify workers in risk analysis and international disease reporting. The goals of the seminar include the exchange of information and an ongoing dialogue on risk analysis. An ideal goal would be the creation of a collaborative group that could assist in critiquing and advising in the areas of risk analysis and disease reporting.

The time and need for these risk assessment systems is now! This is the opportunity for these many skills to become a practical reality! And the impact of this is to profoundly change and enhance the way in which international trade in animals and animal products take place. I wish for you, stimulating deliberations and a productive meeting, and am most interested in the ideas which will be expressed during this day.

RISK ANALYSIS AND REGULATION: IMPLICATIONS FOR THE INTERNATIONAL TRADE IN RED MEAT

Stephen Hathaway

Introduction

The primary role of meat inspection programs is to guarantee the safety and wholesomeness of meat marketed both within the country of origin, and internationally. Adherence to the meat hygiene regulations of the national regulatory authority and the regulatory authorities of importing countries is an obviously important part of achieving this goal. Additionally, there should be a cost-effective and efficient allocation of inspection resources so that there is a maximum ability to reduce food-borne hazards (1, 2, 3). This requires that there be "a risk-based allocation of resources, supported by modern technology and a systematic evaluation of the program"(1).

Post mortem meat inspection acts to remove pathological lesions, organoleptic abnormalities and grossly-visible contamination from fresh meat, however, the performance characteristics of traditional inspection procedures are generally unknown (4). Good manufacturing practice limits initial, unseen contamination to as low a level as possible and prevents any subsequent growth during storage and distribution, but abuse at any stage in the food chain can result in a potential hazard to health. Additionally, surveillance programs act to ensure freedom from exposure to residues, but their actual role in preventing risks to human health remains unquantified.

The dearth of quantitative data defining the safety and wholesomeness of fresh meat, or the true risk of exposure of different consumer groups to meat-borne hazards, perpetuates a traditional approach to many aspects of meat hygiene. In contrast, questions are increasingly being asked about the scientific validity and cost-effectiveness of the classical approach to meat inspection. However, national codes of meat inspection continue to be based on classical rules because there is insufficient research to support changes to more science-based programs. In particular, risk assessment in the field of meat hygiene is in its infancy (3).

Additionally, there is considerable frustration in the field of international meat hygiene regulations. Despite numerous calls to "harmonize" international meat hygiene requirements and promote science-based inspection programs, little is currently being achieved. Failure (or inability) to apply the concept of equivalence to comprehensive inspection programs carried out by different regulatory authorities has already led to considerable problems in trade. The future recognition by trading partners of equivalent rather than replicated post mortem inspection programs will, to a large extent, depend on risk assessment methodology.

Risk Analysis

Risk

As the ability of an agricultural system to alter its production and processing environment through scientific and technological change increases, the need to better quantify the risks inherent in these changes increases. Regulatory authorities often have to decide on what is a fair and acceptable risk: to the promoters of the new science and technology, and to the production systems and people that must bear the risk. The common goal is the reduction of risk, or the minimisation of loss/maximisation of gain.

Risk is the potential for realization of unwanted negative consequences of an event, and risk aversion is action taken to control risk (5). The elements of risk are:

(a) a choice of action (exposure to loss), either voluntary or involuntary
(b) a probability (frequency) of loss
(c) a magnitude of loss (character, extent and timing), assessments of which are not value-free.

Catastrophic risk occurs when the probability of the outcome is extremely low but the magnitude of the possible consequences is great. If there is a high level of uncertainty in probability estimates, the magnitude of loss assumes greater importance in evaluating the total risk (6).

A decision tree (Figure 1) can be used to present decision choices as actions and outcomes. The probability distribution for a set of known outcomes may be agreed (risk); or not agreed, and with unknown outcomes (uncertainty). Reducing uncertainty in a system by gaining more information does not necessarily reduce risk.

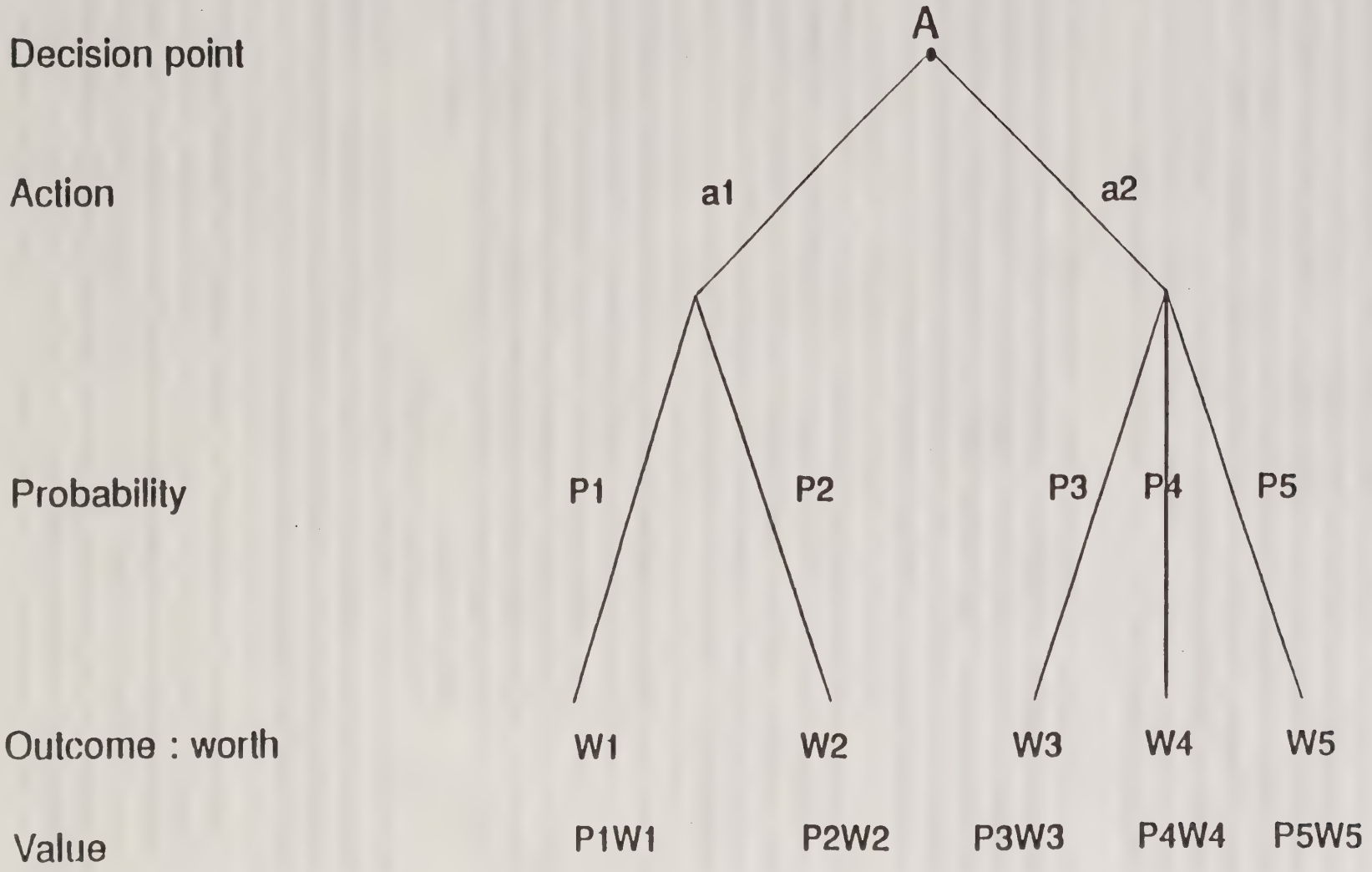
The simplest form of decision analysis uses maximisation of the expected value of each action, i.e., the sum of all the values, as a basis for decision (7). This is risk-neutral and is often more suitable as a basis for regulatory decisions than maximax (risk-prone) or maximin (risk-averse) criteria (8).

However, it should be noted with expected value criterion that multiplication of probability and worth can give the same value of risks that have very different characteristics.

Types of risk have been described by Starr (9):

(a) real risk, which can only be determined in the future
(b) statistical or "actual" risk, calculated from historical data
(c) predicted risk, using analytical models structured from past data
(d) perceived risk, seen intuitively by individuals and subjective in nature.

Figure 1 : A simple decision tree presenting choices as actions and outcomes



Although statistical and predicted risk are regarded as objective measures, they may have subjective elements because of limitations in the quality of data. Statistical methods are inappropriate when very small probabilities are combined with outcomes that are potentially catastrophic, and in this case, predictive models and reliability data are used (7, 10). Some risks that are identified will be so small that they can be regarded as effectively zero. However, accurate estimation of risk, and outcomes of only limited magnitude, are implicit in effective-zero ratings.

Risk Assessment

The determination of acceptable risk is increasingly dependent on quantitative models which are used to set numerical levels below which an estimated risk is considered acceptable. No determination of acceptable risk is valid without consideration of the expected benefit. When human values e.g., health and safety, are involved, the difference between scientifically-evaluated risk and perceived risk may be large and a level of acceptable risk may be difficult to determine.

Risk assessment combines the quantitative process of risk estimation with a subjective evaluation of the risks. Risk estimation is the identification of all possible sources of risk and outcomes, and their quantification in terms of probability and magnitude. Risk evaluation includes interpretation of the significance of risks, and determining levels of acceptable risk. Methods classified by Rowe (11) are:

(a) Risk comparison methods, incorporating known and acceptable risk levels. Historical data, modeling, or perceived risk estimates can be used.
(b) Cost-effectiveness of risk reduction, considering direct costs and benefits. This methods attempts to maximize risk reduction given a fixed budget.
(c) Cost-risk-benefit balancing, weighing all direct and indirect benefits. Acceptable risk is determined by weighing the benefits against the level of risk presented.
(d) Combinations of approaches.

Fischoff (12) adds risk aversion as a method of risk evaluation. A maximum reduction in risk is sought with no consideration of benefits, and no comparison with other risks. This may result in a zero-tolerance standard.

A risk assessment is completed by communicating the results to interested parties and proposing effective controls to monitor the selected actions. Risk management is the process whereby a regulatory agency decides what to do about the results of a risk assessment, and implements these decisions. Economic, social, and political considerations may result in the setting of priorities and the design of regulations that are suboptimal in scientific and technical terms.

A risk assessment model for post mortem meat inspection procedures

Post mortem inspection procedures

Current procedures have evoked largely from traditional European procedures and, in many cases, these have been transposed not only geographically, but also across species and age boundaries. Thus, they are often inappropriate to the spectrum and prevalence of diseases and defects present in a particular class of livestock slaughtered in a defined geographical region. This situation is particularly evident in meat production systems slaughtering large groups of livestock that have homogeneous characteristics, e.g., age, weight, and production history.

Where specific procedures are shown to be scientifically-unjustified and wasteful, inspection resources can be reallocated to process control activities that will enhance product safety and wholesomeness (4). Other benefits include increased processing efficiency, decreased wastage of product and recognition of the true indicator function of tissues that may not be intended for human consumption (13). However, it must be noted that in addition to providing benefits, application of the risk assessment process may expose previously unrecognized problems.

Risk assessment model

Health risk assessment is a specific process used to estimate the likelihood that humans or ecological systems will be affected adversely by a chemical or physical agent under a specific set of conditions (14). The principles can be readily adapted to risk assessment of different post mortem meat inspection procedures. Four analytical steps are involved:

Hazard identification: All hazards that could be present in the tissues of interest, and that could be detected by organoleptic inspection procedures, need to be identified. Hazards in meat hygiene include public health hazards, animal health hazards, and aesthetic defects unacceptable to the consumer.

Hazard characterization: In toxicological risk assessments, hazards are often characterized in terms of dose-response relationships. In the case of hazards in meat that are detectable by post mortem inspection procedures, dose/response relationships are an inappropriate way of characterizing risk. Therefore, all conditions that can be detected by post mortem inspection procedures are considered to constitute some level of risk; this is the most severe hazard characterization possible.

Exposure characterization: By standardizing exposure as the presence of any condition that should have been detected by the procedures under investigation, the performance attributes of the individual procedures (sensitivity and specificity) quantify the precise non-detection rates that accompany different post-mortem inspection procedures for a specific class of livestock. This provides the basis for the establishment of an acceptable defect

level based on a scientific assessment of the likely public health, animal health, and aesthetic risks.

Risk characterization: A consideration of the confidence intervals for the difference between non-detection rates, together with a scientific assessment of the consequences of each difference within the confidence intervals, provides the basis for the risk characterization. In any comprehensive risk characterization, the investigator must consider the importance of all individual lesions that are missed during the application of particular procedures. In the case of tissues that are not destined for human consumption, the only abnormalities of significance are those that serve an indicator function for other tissues.

Field trials

When a change in meat inspection procedures is proposed, a specific field trial must be carried out to quantify any changes in non-detection rates of hazards in the tissue of interest. Very few trials of adequate design have been carried out and important considerations are:

1. Samples must be representative of the population to which the conclusions are to relate. Non-detection rates will depend as much on the prevalence of hazards in the slaughter population as on the performance attributes of the inspection procedures, so the sample has to be designed to give a reliable estimate of this prevalence.

2. The trial should include enough samples so as to give definite conclusions as to the consequences of changing the inspection procedures. However, the larger the sample size, the more difficult and costly the investigation becomes. The upper limit to the sample size is determined by the need to demonstrate that a particular procedure will detect at least one hazard of importance that may occur at a very low prevalence in the slaughter population. For example, a sample size of 29,956 is needed to limit (at the 95% confidence level) the residual risk of non-detection of an important hazard to less than 1:10,000.

3. If possible, all tissues should be inspected by each of the procedures to be compared (full matching) and this involves detailed recording systems to ensure that all relevant inspection data is independently recorded at each inspection station. In a processing environment where line speeds are high, it is often only possible to apply one procedure to the tissues not rejected by the other (negative matching). In this case, tissues found to be positive at the first inspection station are not returned to the processing line for reinspection at the second inspection station. This design forgoes some statistical power, however, evaluation of many inspection procedures involves comparisons between different intensities of inspection (e.g., visual examination, compared with visual examination plus palpation) rather than comparisons between

alternative inspection procedures. Negative matching is a practical and reliable design in such cases, where it can be assumed that all material rejected by the less intense inspection would be rejected by the more intense inspection. Collation of inspection data derived from full matching and negative matching trial designs is shown in Tables 1 and 2.

4. Calculation of true performance attributes is only possible if, after inspection, all tissues are subjected to detailed inspection. This usually involves destruction of tissues by multiple incision. No inferences on non-detection rates can be made without determining the true status of all inspected tissues. Laboratory submissions to support gross pathological diagnosis should be incorporated in the trial program at all times.

5. The most important statistic is an estimate of the difference in non-detection rates to be expected between the traditional and the proposed procedures, together with a suitable confidence interval. A decision on the acceptability of the proposed new procedures can then be based on a consideration of the worst case included in the confidence interval (Tables 1 and 2).

Application of the risk assessment model

Application of a predictive risk model to inspection procedures for the viscera of lambs slaughtered in New Zealand illustrates the risk assessment approach. The health status of the lamb slaughter population has some unique features. New Zealand is free of all List A diseases of the International Office of Epizootics (OIE) and no arboviral or rickettsial zoonoses have been recorded. Extensive surveys have shown the absence of Mycobacterium bovis infection in slaughtered lambs (3). Post mortem meat inspection judgements are harsh, and there is a strong emphasis on human and animal health rather than economic worth.

The results of the three-year research program involving more than 963,000 comparative evaluations of lamb viscera in 37 export slaughterhouses (3) are summarized in Table 3. Notwithstanding the international inconsistencies in different codes for inspection for the viscera of lambs (Table 3), it was demonstrated that many traditional procedures have no scientific justification when applied to lambs slaughtered in this geographical region. In particular, routine examination of some regional lymph nodes of the viscera contributed no extra information on product disposition to that gained by inspection of the primary organs. In the absence of an indicator function, detailed examination of some tissues not intended for human consumption was similarly unjustified and wasteful.

Inspection procedures for the spleen provide a specific example. All cases of concurrent pathological involvement of the spleen and other tissues were detected by visual examination alone. The spleen did not provide any assistance in reaching a disposition for other viscera and/or the carcass when there were concurrent pathological conditions.

Table 1. Analysis of data from a field trial incorporating a full matching design.

	Outcome of Procedure 1	Outcome of Procedure 2	
		+	-
Normal tissue	+	a	b
Normal tissue	-	c	d
Abnormal tissue	+	e	f
Abnormal tissue	-	g	h

Difference in non-detection rates: $D = \frac{f+h}{b+d+f+h} - \frac{g+h}{c+d+g+h}$

Approximate standard error:

$$S = \sqrt{\frac{(f+h)(b+d)}{(b+d+f+h)^3} + \frac{(g+h)(c+d)}{(c+d+g+h)^3} - \frac{2\,h(b+d)(c+d)+d(f+h)(g+h)}{(b+d+f+h)^2(c+d+g+h)^2}}$$

Approximate 95% confidence interval: $D \pm 2S$

Table 2. Analysis of data from a field trial incorporating a negative matching design.

Outcome: Procedure 1	Outcome: Procedure 2	Normal Tissue	Abnormal Tissue
+	+/-	a	b
-	+	c	d
-	-	e	f

Decrease in non-detection rate: Procedure 2 following Procedure 1:

$$D = \frac{d+f}{c+d+e+f} - \frac{f}{e+f}$$

Approximate standard error: $S = \sqrt{\frac{(c+e)(d+f)}{(c+d+e+f)^3} + \frac{ef(c+d-e-f)}{(c+d+e+f)(e+f)^3}}$

Approximate 95% confidence interval = $D \pm 2S$

Table 3: Post mortem inspection procedures for the viscera of lambs

Tissue	New Zealand			European Community	United States	Australia	Codex
	Traditional	Risk Assessment	New				
Liver	O/P	No Change between traditional and new procedures	O/P	O/P	O/P	O/P	O/P
Bile duct	O/P		O/P	I	I	I[b]	-
Heart	O/P		O/P	O	O/P	O/P	O
Pericardium	O		O	O	-	-	-
Gastro-intestinal tract	O		O	O	O	O[c]	O
Lungs	O/P	Lesser intensity of inspection	O	O/P	O/P	O/P	O/P
Kidney	O/P		O	O[d]	O/P	O/P	O
Spleen	O/P		O[c]	O/P	O	O[c]	O
Hepatic lymph nodes	O/P		O	O/P	-	-	O/P
Bronchial/mediastina lymph nodes	P	Unjustified routine procedures	-[c]	P	P	O/P	O/P
Mesenteric lymph nodes	O/P		-[c]	O	O	-	O
Esophagus	O/P		-	O	O	-	-

a O = observe; P = palpate; I = incise
b Incise only in animals found or suspected of being infected with Fasciola hepatica
c Observe only in tissues intended for human consumption
d Enucleation not required
e General viewing during inspection of the lungs or gastrointestinal tract

The addition of palpation to the visual inspection process resulted in a decrease in the non-detection rate for all abnormalities of 1.11 per 1000 spleens that would be passed for human consumption. The best possible care using 95% confidence intervals would be a decrease of 1.49 per 1000. The small increase in performance with the addition of palpation was related almost exclusively to trivial aesthetic defects (fibrous tags and trauma). When abnormalities of possible public health importance alone were considered, the addition of palpation decreased the non-detection rate in the best possible case by 0.01 per 1000 spleens that would pass inspection. This decrease related to infarcts alone; abnormalities of very questionable importance with respect to constituting a possible hazard to human health. Thus, the risk assessment model clearly demonstrated that routine inspection of the spleen of lambs slaughtered in New Zealand is not necessary if the tissue is not retained for human consumption. If the spleen is retained, inspection should be limited to visual examination alone.

Contaminants

In the past, the threat to human health posed by various grossly-evident diseases has been overemphasized relative to the threat posed by inadvertent microbiological contamination of the carcass and offals. It has also become apparent that microbiological sampling focused on the end product is of only limited effectiveness in achieving continuous process control.

The Hazard Analysis Critical Control Point (HACCP) approach utilizes risk assessment to identify and rank any points or procedures in a specific food system where loss of control may result in an unacceptable health risk. These points or procedures are designated critical control points, and a formal system for monitoring critical limits and verifying that the process is in control is established. HACCP is now well established in the general sphere of food processing and it is likely that will become an important part of regulatory frameworks for meat inspection in the future (15, 16).

Although food hygienists consider that chemical residues and animal drugs are much less significant hazards than microbiological contaminants, regulatory authorities retain an important responsibility in preventing their entry into the food chain. These substances reduce the cost of producing food, however, risk assessments are often necessary to determine what level of residues are acceptable in the final product. The risks to human health depend on how toxic the substance is, the level of residue in a particular product, and the amount of that product likely to be eaten by an individual consumer.

Risk estimates for chemical residues involve many scientific and technical uncertainties, but are usually based on very conservative assumptions. Risk estimates should not be construed as true consumer risks, but they do provide an index of priorities. However, there is an inevitable political input into the setting of some residue limits and in some cases artificially-high maximum residue levels have been set where politics (or what is achievable at a regional level) have intruded into risk assessments. It should also be noted that at

current testing levels, any hazard that exists at a prevalence of less than 1:100 in the target population is likely to go undetected. This low intensity of surveillance obviously has a marked effect on the risk of consumer exposure. All hazards can never be eliminated, but whether or not the consumer is prepared to fund more expensive surveillance programs to bring about a reduction in risk is a matter for public policy debate.

Codex Alimentarius

The present General Agreement on Tariffs and Trade (GATT) round that has been addressing sanitary and phytosanitary issues has provided a new focus for discussion on international science-based standards for meat hygiene. These should, in large part, be developed by Codex Alimentarius, whose code of practice can provide a vehicle for reducing non-tariff trade barriers resulting from different national regulations. In arriving at recommendations on safety criteria, the balance between risks and benefits must be established and Codex pays significant regard to the social and economic costs involved in meeting the standards it recommends.

The risk assessment approach to determining appropriate post mortem inspection procedures for a specified class of slaughtered livestock from a particular geographical region has recently been introduced into the Codex meat hygiene codes of practice. In addition, the HACCP approach to process control is being introduced to all appropriate Codex food hygiene codes of practice. New codes will facilitate a positive regulatory response to scientific advances in meat hygiene based on risk assessment, and help identify where that response has been overridden by socioeconomic factors, consumer psychology, or politics.

Conclusion

The newly-emerging discipline of risk assessment has wide application in the field of meat hygiene. Regulatory authorities are increasingly faced with public policy decisions that must assess the risks of new science and technology relative to the potential benefits; thereby establishing levels of acceptable risk. Determination of these levels is increasingly dependent on quantitative models. All models have some degree of subjectivity, and the decisions made by regulatory authorities should incorporate a wide knowledge of the risk assessment process, and the conditions of use that will occur in the real world.

Contamination of meat with enteric pathogens has emerged as the dominant cause of meat-borne zoonoses, and reallocation of resources within meat inspection programs is required to combat this source of hazards. The risk assessment process provides a particularly valuable tool to identify those post mortem inspection procedures that are unscientific and wasteful and which should be discontinued.

Where inconsistent and scientifically-unproven national requirements persist and scientific data is presented that may validate an equivalent (or better) meat inspection program, a

dispute may arise over acceptance of the risk assessment methodology used to develop that program. Conversely, the legislative inability of an importing country to accommodate inspection programs that do not replicate their own may be advanced as a reason for non-acceptance. In the former case, there is a need for internally-accepted risk assessment methodology to govern experimental studies. In the latter case, regulatory authorities should advocate rule-making or legislative changes that allow recognition of science-based and equivalent inspection meat programs.

References

1. Anonymous. 1985. Meat and poultry inspection: The scientific basis of the nation's program. National Research Council. National Academy Press, Washington, DC.

2. Anonymous. 1989. Report and resolutions. In Proceedings of the 10th Symposium of the World Association of Veterinary Food Hygienists, Stockholm, 2-7 July.

3. Hathaway, S.C. and McKenzie, A.I. 1989. Evaluation of post mortem meat inspection procedures for sheep slaughtered in New Zealand. Volume 1. The viscera of lambs. New Zealand Ministry of Agriculture and Fisheries, Wellington.

4. Hathaway, S.C. and Pullen, M.M. 1990. A risk assessment approach to the evaluation of post mortem meat inspection procedures for ovine thysanosomiasis. J. Amer. Vet. Med. Assoc., 196: 860-864.

5. Rowe, W.D. 1977. An anatomy of risk. John Wiley and Sons, London.

6. Anonymous. 1986. Determining risks to health: federal policy and practice. United States Department of Health and Human Services. Auburn House, Massachusetts.

7. Gough, J. 1988. Risk and uncertainty. Information Paper Number 10. Centre of Resource Management, University of Canterbury, New Zealand.

8. Daellenbach, H., George, J. and McNickle, D. 1983. Introduction to operations research techniques (Second Edition). Allyn and Bacon, Boston.

9. Starr, C., Rudman, R. and Whipple, C. 1976. Philosophical basis for risk analysis. Ann. Rev. Energy, 1: 652-662.

10. Paustenbach, D.J. 1989. The risk assessment of environmental and human health hazards: a textbook of case studies. John Wiley and Sons, New York.

11. Rowe, W.D. 1980. Risk assessment approaches and methods. In Society, technology and risk assessment, J. Conrad, ed. Academic Press, London. pp 3-29.

12. Fischoff, B., Hohenenser, C. and Kasperson, R. 1980. Handling hazards. Environment, 20: 7-12.

13. Hathaway, S.C. and McKenzie, A.I. 1989. Impact of ovine meat inspection systems on processing and production costs. Veterinary Record, 124: 189-193.

14. Anonymous. 1983. Risk assessment in the Federal Government: Managing the process. National Research Council, National Academy Press, Washington, DC.

15. Clarke, G.C. 1989. The hazard analysis critical control point (HACCP) approach to slaughter quality control in red meat abattoirs. In Proceedings of the 10th International Symposium of the World Association of Veterinary Food Hygienists, Stockholm, 2-7 July. pp 194-198.

16. Prucha, J.C., Hollingsworth, J. M. and James, W. O. 1989. The application of HACCP to poultry inspection: status report of a feasibility study. In Proceedings of the 10th International Symposium of the World Association of Veterinary Food Hygienists, Stockholm. 2-7 July. pp 201-205.

RISK ANALYSIS AND THE IMPORTATION OF ANIMALS

Stuart C. MacDiarmid

In November 1990 in New Zealand, sheep descended from animals imported from Denmark and Finland in 1984 were released from quarantine. The first of these Scandinavian-origin sheep were imported as embryos (1) because this method was considered to reduce significantly the risks of introducing unwanted disease along with the new bloodlines (2, 3). However, the final release of these exotic sheep has provoked, once again, expressions of concern from some farmers' groups who believe that Ministries of Agriculture and Fisheries (MAF) has somehow changed its policies and retreated from a "no risk" approach to quarantine. Such questioning has also been provoked by recent importations of sheep and goat embryos from Zimbabwe, llamas and alpacas from Chile, and sheep embryos from Israel.

MAF does not operate a no risk quarantine policy (2). There is only one no risk policy and that is total exclusion of all imports (2, 4). Furthermore, even a total prohibition on importation of animals and animal products would not achieve zero risk because people still travel, and if legal avenues are unavailable, people will find ways to import illegally. Additionally, in the current global climate of reducing barriers to trade, non-tariff trade barriers are coming under closer scrutiny and a country like ours, which depends so heavily on exporting agricultural products, cannot hope to maintain continued access to important markets while still denying entry to imports from other countries. Trade in animals and animal products is going to occur. It is the role of quarantine to facilitate this trade while at the same time assessing systematically the risks associated with imports and reducing those risks to an acceptable level.

When analyzing the risks associated with a proposed importation of animal genetic material (be it live animals, embryos, or semen) it must be remembered that such imports cannot be made without some element of risk (4, 5). The benefits of the imports often accrue to a relatively small group of people only, usually the entrepreneurs, initial importers, and distributors of the new genetic material (5). The risks, on the other hand, are borne by a much broader group, which includes all livestock owners whose animals could be infected with an exotic disease agent, as well as the general public, who could be expected to bear the cost of containing and eradicating an outbreak of exotic disease (4, 5). For these reasons a risk analysis should, ideally, include a cost-benefit analysis of the proposed importation.

In determining whether or not to allow a proposed import to proceed, MAF must identify the risks involved, attempt to quantify them, and then design a series of safeguards sufficient to reduce the risk to an acceptable level.Risk analysis is a blend of art and science and combines risk identification, [also known as hazard identification], risk assessment, risk

management, and risk communication. Risk identification and risk communication will not be discussed in this article.

Risk, as it relates to the importation of animals or animal products, is a measure of the probability of the introduction of an exotic disease and the seriousness of such an outcome. *Risk assessment* is the process of estimating, as objectively as possible, the probability that an importation would result in the entry of an exotic disease agent and that local livestock would be exposed to that agent. *Risk management* is the process by which the risk is reduced.

The first stage in risk analysis is an assessment of the risk entailed by an unrestricted importation of animals or products under consideration. Risk assessment takes into account the prevalence of pathogens in the source population, the probability of pathogens surviving in the animal or product during the process of importation, the probability of the pathogen coming into contact with local livestock after importation, and the seriousness of such contact. Theoretically, each of these factors should be amenable to being qualified in an objective and scientific fashion. In reality, it is seldom possible to quantify them adequately. Much of the assessment ends up being based on guesswork and is thus potentially controversial and open to challenge from either domestic interest groups or overseas trading partners. Risk management, on the other hand, is usually able to be quantified more objectively. For instance, there should be very little debate over the sensitivity of a particular serological test, or the efficacy of a particular embryo washing regimen for a specific pathogen on embryos of a given species.

Consider, for example, a serological test having a sensitivity of 0.95 when applied to animals infected with a particular disease agent. The probability, therefore, of missing a single infected individual is 0.05.

However, the predictive value of a diagnostic test is also a function of the prevalence of infection in the population under test. The probability that an animal which is negative to a given test is actually infected is calculated as follows (6);

EQUATION 1:

$$\text{Prob}\,(I|N) = \frac{p\,(1-s)}{p\,(1-s) + (1-p)e}$$

where I is infected animals, N is non-reactor animals, p the true prevalence, e the specificity of the test, and s the test sensitivity.

In matters of quarantine, the exclusion of "false positive" animals is not usually of major concern, so for the purposes of this discussion let us assume that specificity is 1 (i.e., $e = 1$). With the same test referred to above, where $s = 0.95$, the probability of a given test-negative animal actually being infected varies with prevalence, p, as illustrated in Table 1. It

can be seen that as the prevalence of infection in the source population increases, the probability of a given test-negative animal being infected also increases.

TABLE 1 - Probability that a test-negative animal is actually infected, given a test sensitivity 0.95 and specificity 1

PREVALENCE	PROBABILITY (I/N)
0.01	5.05×10^{-4}
0.05	2.62×10^{-3}
0.1	5.52×10^{-3}
0.2	1.23×10^{-2}

Similarly, at any given prevalence, the probability of including a test-negative infected animal in an importation increases with the number of animals in the group to be imported. Marchevsky and coworkers(6) have shown that the probability of including even one test-negative infected animal (c) in a group of n animals can be calculated thus;

EQUATION 2:

$$\text{Prob}\ (c \geq 1 | N) = 1 - \left[\frac{(1-p)e}{(1-p)e + p(1-s)}\right]^n$$

The effect of increasing the size of the group destined for import is illustrated in Table 2.

With some diseases a policy decision may be made that a positive test result will disqualify only the individual animal which reacted positively to the test. The risks one takes with such a policy are illustrated in the examples just discussed (Tables 1 and 2). However, with some other diseases, it may be decided that a positive test result in any one animal will disqualify the entire group intended for importation. In such cases the probability of disqualifying an infected group increases as prevalence and/or the size of the group increases. Thorburn and her colleagues(7) proposed that the probability that all animals in an infected flock or herd, size n, will test negative can be calculated thus:

EQUATION 3:

$$\text{Prob}\ (R=0) = [p(1-s)+(1-p)e]^n$$

TABLE 2 - Probability that a test-negative infected animal will be included in a group destined for import when only reactor animals are excluded (Prevalence = 0.01, sensitivity = 0.95, specificity = 1)

n	PROBABILITY ($c \geq 1 \mid N$)
10	5.04×10^{-3}
20	1.00×10^{-2}
30	1.50×10^{-2}
50	2.49×10^{-2}
100	4.92×10^{-2}
500	2.23×10^{-1}

The difference in risk between the two policies is illustrated in Table 3. It can be seen that where the presence of a single reactor animal disqualifies the entire group destined for export, rather than just the reactor animal itself, the risks of an infected animal being imported are significantly reduced.

Table 3 - Probabability that a test-negative infected animal will be included in a group destined for import (prevalence = 0.01, sensitivity = 0.95, specificity = 1)

n	If reactor animal only excluded Prob ($c \geq 1 \mid N$)	If a single reactor disqualifies group Prob ($R = 0$)
300	1.41×10^{-1}	5.71×10^{-2}
400	1.83×10^{-1}	2.20×10^{-2}
500	2.23×10^{-1}	8.45×10^{-3}

However, although logic dictates that the policy of disqualifying the whole group, if even one reactor occurs, is a lower risk policy than when only reactors are disqualified, the equations used above are not actually calculating the same thing and so are not strictly comparable. Equation 2 calculates the probability that one or more infected test-negative animals will be included in the group while equation 3 calculates the probability *that no reactors will occur.* These are not the same thing. One expects reactors will occur in an infected group, even if a test has a relatively low sensitivity.

Because the different equations calculate the probabilities of different events, comparisons of the type made in Table 3 will not maintain the same relationship over a wider range of values for group size, n. With the same values for prevalence, sensitivity, and specificity, the relative magnitude of the probabilities does not hold below a group size of around 250.

Whether a positive result to any one test disqualifies only the affected individual or the whole importation, the risks of importing unwanted disease can be further reduced by imposing a series of safeguards. When a series of safeguards is applied to an importation it may be relatively easy to quantify the amount by which the risk is reduced, even if consensus on the magnitude of the initial, unrestricted risk cannot be attained.

Reducing the risk of scrapie

At this point it is appropriate to look at some examples of risk management.

Apart from cases in imported sheep in 1952-54 and 1976-77, New Zealand has remained free of scrapie (8). Apart from some importations from Australia, also scrapie-free, the release from quarantine of Scandinavian-origin sheep in late 1990 was the first infusion of new genetic material into the New Zealand sheep population in over 40 years.

The Scandinavian imports were from countries free of scrapie (Denmark and Finland). However, interest has been expressed in importing bloodlines from countries where scrapie is present. What follows is an outline of a chain of risk-reducing safeguards which could be imposed to permit the importation of sheep genetic material while still safeguarding New Zealand's scrapie-free status.

Let us assume, at least at this stage, that the initial risk, P(I), is unknown and equal X.

The first safeguard (SG_1) is a requirement that all donors be over 5 years of age. We know that at least 70% of scrapie sheep exhibit disease before 5 years of age (9, 10, 11), so SG_1 reduces the risk to 30% of the original level. That is,

$$P(\text{I} \mid \text{importing sheep} > 5 \text{ years of age}) = 0.3X$$

The second safeguard (SG_2) is embryo transfer. Studies in the United States have indicated that scrapie is unlikely to be transmitted by embryo transfer (12). By February 1989, 29 sheep, born from ewes implanted with embryos collected from scrapie donors, were still alive and scrapie-free after more than 60 months (W. C. Foote, pers. comm.). A worst-case interpretation of this result suggests that we can be 95% confident that embryo transfer from scrapie donors will not transmit the disease in more than 12% of transfers (13). This means that SG_2 (embryo transfer) = 0.12. So,

$$P(\text{I} \mid \text{importing embryos} \cap \text{donors} > 5 \text{ years of age}) = 0.036X$$

[A simplification has been made in the calculations at this point. It is usual that each donor produces a number of embryos, several of which may develop into lambs. Should a donor be infected with scrapie, the likelihood of her passing the disease on increases with an increase in number of offspring. However, the more infected offspring that are born in

quarantine, the greater the probability of at least one exhibiting signs of scrapie before the termination of quarantine.]

The third safeguard (SG_3) is a bioassay using goats inoculated intracerebrally and intraperitioneally with a homogenate of lymph nodes, spleen and brain tissue collected from the embryo donor animals. Studies with Suffolk sheep have demonstrated that scrapie agent is likely to be present in a pool of these tissues from most, if not all, cases of preclinical scrapie (14). Other experiments have demonstrated that most, if not all, goats inoculated with such a pool by the intracerebral and intraperitoneal routes will develop clinical scrapie within a 30 month period (15, 16) On the basis of these published studies and personal communication with workers overseas, we believe that goat bioassay can be expected to detect 80% of preclinical scrapie cases. This means that $SG_3 = 0.2$, resulting in:

$$P(I \mid \text{importing embryos} \cap \text{donors} > 5 \text{ years of age} \cap \text{donors are bioassay negative}) = 0.0072X.$$

Holding the group of embryo-derived sheep in quarantine until all are older than 5 years would result in a further 70% reduction in risk. That is, $SG_4 = 0.3$ and,

$$P(I \mid \text{importing embryos} \cap \text{donors} > 5 \text{ years of age} \cap \text{donors are bioassay negative} \cap \text{offspring} > 5 \text{ years of age}) = 0.0022X.$$

If the initial risk X is the same as the prevalence, P, in the flock of origin, then this chain of safeguards has reduced the risk to 0.0022P. That is, if the prevalence in the flock of origin was, say, 20%, the risk of any individual having scrapie after satisfying these quarantine safeguards would be less than 1 in 2,000. However, even this figure overstates the risk because the detection of even a single case of scrapie at any stage of this chain of safeguards would result in the termination of the entire importation.

Reducing the risk of Maedi visna

Maedi visna, or ovine progressive pneumonia (OPP), is a retrovirus infection of sheep which is present in many, if not most, of the countries from which sheep might be imported. The major route by which Maedi visna spreads is through the milk of the dam to her lamb. The virus is almost entirely cell associated in lymphocytes, and spread between adult sheep is uncommon. Spread by respiratory droplets may occur however, especially under conditions of close confinement. Other concurrent respiratory disease may facilitate the spread of Maedi by aerosol. *In utero* infection may occur, but is considered rare (17).

In common with other retrovirus infections, Maedi visna has a prolonged period between infection and seroconversion. Seroconversion may take many months (17). However, the serological tests available have relatively good sensitivity and are reasonably reliable in

animals over twelve months of age (D. J. Houwers, R. E. Oliver, pers. comm.). It is likely that up to 5% of infected sheep fail to seroconvert.

Studies on the transmission of maedi visna virus by embryo transfer have not yet been published. However, a very small study with the closely-related virus of caprine arthritis encephalitis (CAE) failed to demonstrate transmission of infection (19). A large number of studies have shown that enzootic bovine leucosis (EBL) virus is not transmitted along with embryo transfers (20) and, as the maedi visna virus and EBL virus are both almost entirely cell-associated, it is valid to assume that the risk of transmitting maedi visna virus is similarly remote.

As in the scrapie example, we shall assume that the initial risk, P(I), is unknown. That is, equals X.

The first safeguard is a serological test (ELISA) for evidence of Maedi visna infection in the donor ewe. The probability that this test will detect infection in animals over 12 months of age is taken as 0.95, so $SG_1 = 0.05$ and:

$$P(I|\text{donor ELISA negative}) = 0.05X$$

The second safeguard is embryo transfer. By analogy with enzootic bovine leucosis (see above), for which over 2,000 embryo transfers from infected donors have been made without transmitting infection (20), we can be 95% confident that embryo transfers will not transmit the disease in more than 0.4% of transfers (13). That is, $SG_2 = 0.004$ and;

$$P(I|\text{importing embryos} \cap \text{donor ELISA negative}) = 0.0002X$$

The third safeguard against introducing Maedi visna would be to hold the lambs produced from the embryo transfers in quarantine and test them serologically when they are more than two years old. The probability of infected sheep seroconverting in two years is greater than 0.9. That is, $SG_3 = 0.1$ and:

$$P(I|\text{importing embryos} \cap \text{donors ELISA negative} \cap \text{offspring ELISA Negative at 2 years of age}) = 0.00002X$$

It can be seen that even if the prevalence of Maedi visna is high in the donor flock, the risks of introducing the disease are very slight. With these safeguards, the risk of introducing Maedi visna would be around one in 100,000 sheep, even if 50% of the donor flock were infected.

'Acceptable' risk

Even in situations where the risk from unrestricted entry can be quantified objectively, and little controversy surrounds the calculation of the extent to which safeguards reduce that

risk, it may be difficult to attain agreement on what constitutes an acceptable risk. What is an acceptable business risk to the entrepreneur may be quite unacceptable to the representatives of the established livestock industries. Table 4 lists some commonplace risks of human fatality (21). It can be seen that people routinely take risks with their own lives and these risks are of a similar order of magnitude to those just estimated for the introduction into New Zealand of two exotic diseases.

Table 4 - Some Commonplace Risks Of Human Fatality (adapted from Wilson and Crouch, 1987 (20)

EVENT	MEAN ANNUAL RISK
Motor vehicle accident (total)	2.4×10^{-4} (2.4 in 10,000)
Motor vehicle accident (pedestrian only)	4.2×10^{-5} (4.2 in 100,000)
Home accidents	1.1×10^{-4} (1.1 in 10,000)
Electrocution	5.3×10^{-6} (5.3 in 1,000,000)
Cigarette smoking (one pack per day)	3.6×10^{-3} (3.6 in 1,000)
Peanut butter (four tablespoons per day)	8.0×10^{-6} (8 in 1,000,000)
Alcohol (light drinker)	2.0×10^{-5} (2 in 100,000)
Mountaineering	6.0×10^{-4} (6 in 10,000)

To conclude, I offer the following parable (22). "The young man could open either of two doors. If he opened the one, there would emerge a hungry tiger, the fiercest that could be procured, which would immediately tear him to pieces. But if he opened the other door, a beautiful lady would come forth, a lady ideally suited to the young man's years and station.

"So, which door should the young man open? The first man refused to take the chance. He lived safe and died chaste.

"The second man hired risk assessment consultants. He collected all available data on lady and tiger populations. He brought in sophisticated technology to listen for growling and detect the faintest whiff of perfume. He completed check-lists. He developed a utility function and assessed his risk averseness. Finally, sensing that in a few more years he would be in no condition to enjoy the lady anyway, he opened the optimal door. And was eaten by a low probability tiger."

"The third man took a course in tiger taming. He opened a door at random and was eaten by the lady."

The moral of the story is this: "Those who seek a risk free society have little interest in quantification of the level of risk. Available technology may correctly assess the probability

of a hazard but it cannot provide certainty for decision makers. Most important of all is the difficulty of perceiving all possible risks."

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References

1. Tervit, H. R., Baker, R. L., Hoff-Jorgensen, R., Lintukangas, S., MacDiarmid, S. C., and Rainio, V. 1986. Viability of frozen sheep embryos and semen imported from Europe. In proceedings of the New Zealand Society of Animal Production, 46: 245-250.

2. O'Hara, P. J. 1987. Animal Imports - Have We Changed Our Policy? Surveillance, 14 (1): 3-4.

3. MacDiarmid, S. C. 1988. Embryo Transfers and the Transmission of Diseases. Surveillance, 15 (5): 10-11.

4. Department of Primary Industries and Energy. 1988. Australian Quarantine Requirements for the Future. A report by the Quarantine Review Committee. Australian Government Publishing Service, Canberra.

5. Acree, J. A. and Beal, V. C. 1988. Animal Health Perspectives of International Embryo Exchange. Animal & Human Health, 1 (1): 39-44.

6. Marchevsky, N., Held, J. R. and Garcia-Carrillo, C. 1988. Probability of Introducing Diseases Because of False Negative Test Results. American Journal of Epidemiology, 130: 611-614.

7. Thorburn, M. A., Mc Dermott, J. J. and Martin, S. W. 1991. Probability of Introducing Diseases Because of False Negative Test Results. American Journal of Epidemiology, 133: 321.

8. Bruere, A. N. 1985. Scrapie in New Zealand - Its History and What It Could Mean. In proceedings of the New Zealand Veterinary Association Sheep and Beef Cattle Society, 15th Annual Seminar, Invercargill. 23-24 May. pp 9-22.

9. Parry, H. B. 1962. Scrapie: A Transmissible and Hereditary Disease of Sheep. Heredity, 17: 75-105.

10. Dickinson, A. G. 1976. Scrapie in Sheep and Goats. In Slow Virus Diseases of Animals and Man, ed. by Kimberlin. North-Holland, Amsterdam. pp 209-241.

11. United States Department of Agriculture. 1988. Quantitative Risk Assessment of BSE/APHIS/VS Animal Health Information in the United States. Fort Collins. p 6.

12. Foote, W. C., Call, J. W., Bunch, T. D. and Pitcher, J. R. 1986. Embryo Transfer in the Control of Transmission of Scrapie in Sheep and Goats. In Proceedings of the United States Animal Health Association, 19: 413-416.

13. Diem, K. 1962. Scientific Tables. 6th edition, Geigy Pharmaceuticals, St. Leonards, New South Wales. p 86.

14. Hadlow, W. J., Kennedy, R. C. and Race, R. E. 1982. Natural Infection of Suffolk Sheep with Scrapie Virus. Journal of Infectious Diseases, 146: 657-664.

15. Pattison, I. H., Gordon, W. S. and Millson, G. C. 1959. Experimental Production of Scrapie in Goats. Journal of Comparative Pathology, 69: 300-312.

16. Pattison, I. H. and G. C. Millson. 1962. Distribution of the Scrapie Agent in the Tissues of Experimentally Inoculated Goats. Journal of Comparative Pathology, 72: 233-244.

17. Houwers, D. J. 1988. Ovine Lentivirus Infections. Drukkerij Elinkwijk, B. V., Utrecht.

18. Houwers, D. J. and Oliver, R. E. Personal communication.

19. Wolfe, D. F., Nusbaum, K. E., Laverman, L. H., Mysinger, D. W., Riddell, M. G., Putnam, M. R., Shumway, L. S. and Powe, T. A. 1987. Embryo Transfer from Goats Seropositive for Caprine Arthritis-encephalitis Virus. Theriogenology, 28: 307-316.

20. International Embryo Transfer Society. 1987. Manual of the International Embryo Transfer Society, Champaign, Illinois.

21. Wilson, R., and Crouch, E. A. C. 1988. Risk Assessment and Comparisons: An Introduction. Science, 236: 267-270.

22. Anonymous. 1988. The Lady or the Tiger? New Zealand Engineering. 1 March. p 15.

IMPORT RISK ANALYSIS SYSTEM (IRAS): A SYSTEM TO ASSESS THE ANIMAL DISEASE RISKS ASSOCIATED WITH THE IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS

Randall S. Morley and John A. Acree

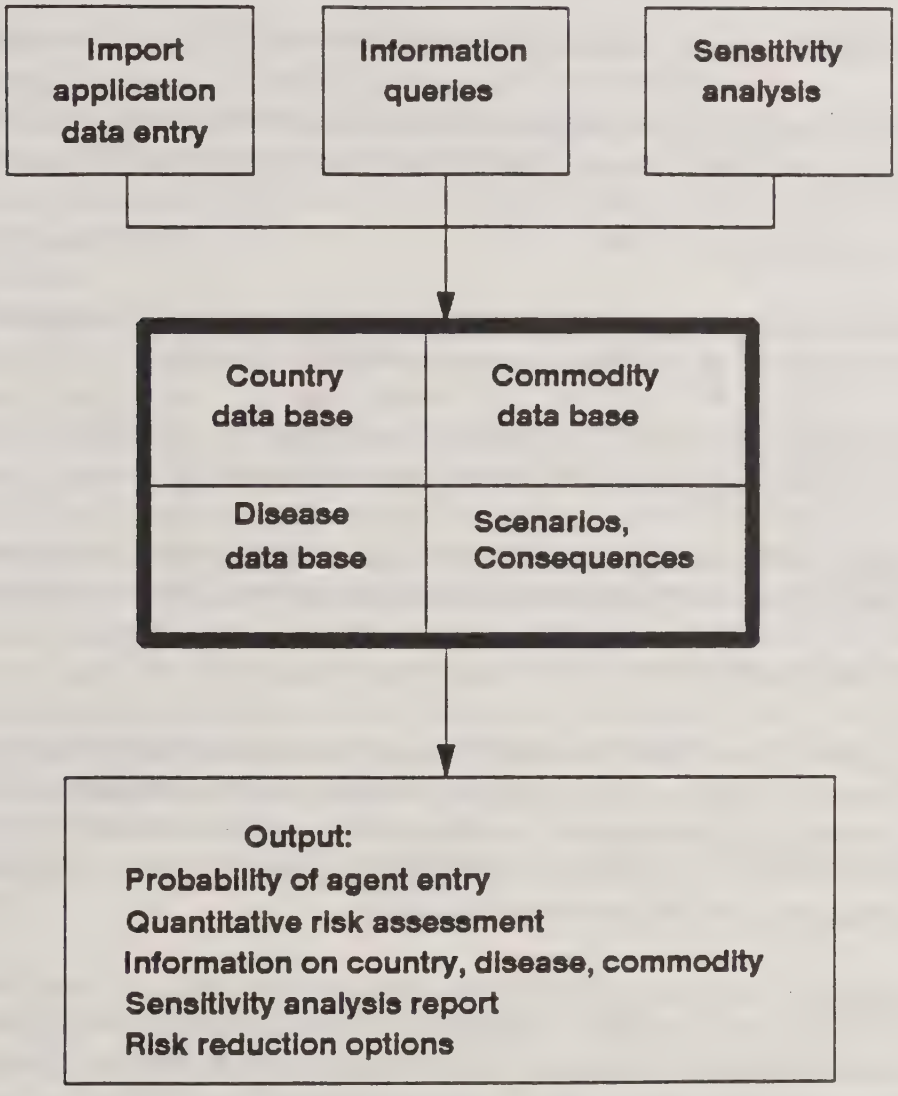
Introduction

The importation of animals and animal products inevitably involves a degree of disease risk on the part of the importing country. Regulators charged with the responsibility of import programs require an objective, repeatable, and defensible method of assessing these risks. IRAS is simple and transparent and provides a systematic approach whereby consistent assessments can be obtained for any importation. Information on animal disease statistics, current outbreak situation, animal and human demographics, veterinary infrastructure, disease control and import policies, disease situation in bordering countries, and the regionalization or area confinement of disease is compiled in a data base of data from member counties of the Office International des Epizooties (International Office of Epizootics), OIE. This is merged with a data bases on the animal and animal product imports and information on all OIE List A and List B diseases pertaining to hosts, agent survival, agent transmission studies, modes of transmission, vectors, persistence of infection, average duration of infection, morbidity, mortality, and the measures that can be applied to reduce the risks associated with an importation. The process assimilates the relevant information for any importation and estimates the risks. Besides the facility to obtain a risk assessment report on any import application, the data bases can be queried for information (see Figure 1).

The exclusion of an animal, animal product, or animal by-product based only on the presence of a disease in an exporting country is not defensible. It ignores the progress countries have made in the control or area confinement of a disease. The level of disease occurrence in the exporting country and the measures that can be applied to prevent introduction of a disease are taken into account with IRAS.

The benefits of risk analysis include protection of the consumer, the livestock producer, the fauna, and the environment from foreign animal diseases, competitive prices for the consumer, producer competitiveness, freer trade, consistent and scientifically documented import decisions, emphasis of the importance of the OIE animal disease reporting system; facilitation of the import of new genetic materials, stimulation of the exchange of animal health information among trading partners, harmonization of import policies among trading partners, and in general, elucidation of the reasons behind import decisions, and, provision of an up-to-date data base on international disease occurrence.

Figure 1. Import Risk Analysis System components



Definitions

Agent - an organism associated with the epidemiology of OIE List A and List B diseases.

Animal Import Unit (AIU) - a live animal or a specified weight of product.

Commodity - an animal, animal product, or animal by-product being considered for import.

Risk - a measure of the likelihood and magnitude of an adverse event, that being the entry, establishment, and spread of a disease agent through the importation of commodities.

Risk Analysis - an inclusive term for:

1) Risk Assessment - the process to identify, estimate the statistical probabilities, and evaluate the consequences of all risks associated with the importation of a commodity;

2) Risk Communication - the process to communicate the risk assessment results to the regulators of the import programs, to industry, and to the public; and,

3) Risk Management - the decision-making process to identify and implement measures that can be applied to reduce the risk and document the final import decision.

Transmission of infection

A. Direct transmission - direct and essentially immediate transfer of an agent to a receptive portal of entry through which animal or human infection may take place. This may be by direct physical contact (e.g., contagious equine metritis, rabies), contact with infected excretions and secretions (e.g., bovine brucellosis, leptospirosis), or contact with respiratory droplets (e.g., contagious bovine pleuropneumonia).

B. Indirect transmission - a) vehicle borne - transfer on an agent to a receptive portal of entry (particularly the gastro-intestinal tract) via the contamination of bedding (e.g., foot and mouth disease), surgical instruments (e.g., iatrogenic transmission of anaplasmosis), feed (e.g., pork meat scraps fed to swine and transmitting hog cholera), or any material or objects by which the agent can be transported and introduced to a susceptible animal or man; b) vector-borne - 1) Mechanical - mechanical carriage of an agent on the exterior or in the proboscis or an arthropod or by passage of the agent through its gastrointestinal tract. Multiplication or development of the agent is not required (e.g., equine infectious anemia). 2) Biological - a vector (arthropod) in which an agent undergoes either a necessary part of its life cycle or multiplication before transmission (e.g., babesiosis, theileriasis) c) Air-borne - transmission of particles, consisting wholly or partially of agent, through the air and frequently over long distances. The portal of entry is usually the respiratory tract (e.g., foot and mouth disease, Aujeszky's disease).

Events and their probabilities

Considering the importation of one Animal Import Unit (AIU), whether it is a live animal or a product equivalent, a number of events occur or states of nature exist which result in the event (O) or disease outbreak, as follows:

A - Animal Import Unit (AIU) is infected with the agent
B - agent survives commodity handling, treatment or intransit time
C - commodity is exposed to susceptible animals or man
D - agent is transmissible via mode of transmission
E - agent induces infection (entry and development or multiplication of the agent)
F - infection induces disease
G - disease spreads
H - disease is detected

This is a generic set of events as each disease with its own epidemiology has a different set of events. For example, anaplasmosis and babesiosis involve vectors, cysticercosis involves more than one scenario of exposure related to the definitive and intermediate hosts, and man may be involved in the transmission of a disease agent from animal or product to animal. As well there are many factors involving the agent, susceptible host, and environment. Agent factors include the infectivity of the strain of agent, the ability of the agent to produce disease (pathogenicity), the virulence or the severity of the disease produced by the agent, the immunogenicity and antigenic stability of the agent and the viability of the agent in the environment. However, for the purpose here, the list of events is an adequate generalization. Based on the scientific evidence available one could determine the probabilities of the events occurring.

P(O) - probability that a disease outbreak occurs following the importation of one AIU of the commodity

$$P(O) = P(A) \bullet P(B|A) \bullet P(C|A \cap B) \bullet P(D|A \cap B \cap C) \bullet P(E|A \cap B \cap C \cap D) \bullet P(F|A \cap B \cap C \cap D \cap E) \bullet P(G|A \cap B \cap C \cap D \cap E \cap F) \bullet P(H|A \cap B \cap C \cap D \cap E \cap F \cap G) = p_1 p_2 p_3 p_4 p_5 p_6 p_7 p_8$$

In words these probabilities are:

P(A) - probability that the AIU is infected with the disease agent, that is, the prevalence of the disease in the exporting country,

P(B|A) - conditional probability of agent survivability given that the AIU is infected,

P(C|A∩B) - conditional probability of exposure of the commodity to susceptible animals or man given that the AIU is infected and the agent survives in the commodity,

$P(D|A \cap B \cap C)$ - conditional probability that the agent is transmissible via mode of transmission given that the AIU is infected, the agent survives in the commodity and the commodity is exposed to susceptible animals or man occurs,

$(PE|A \cap B \cap C \cap D)$ - conditional probability that infection results given that the AIU is infected, the agent survives in the commodity, the commodity is exposed to animals or man and the transmissible, and so on.

When one considers the importation of a group of n AIUs, P(O) is not obtained as a product of a prior and several conditional probabilities but through a computation based on the binomial distribution. The assumption is made that infection within the importing country is possible if at least one of the AIUs infected at the port of entry.

P(O) = P(at least one AIU is infected at port of entry and disease is detected)

$= P(I \cap X) = P(I) * P(X|I)$

where P(I) = probability that at least one AIU is infected at port of entry,

P(X|I) = probability that exposure, transmission, infection, disease, and disease detection occurs given that at least one AIU is infected at port of entry

$= \underline{p_3 * p_4 * p_5 * p_6 * p_7 * p_8}$

Now P(I) = 1 - P (I) = 1 - P (no AIUs are infected at port of entry).

P(I) = P[(none of the AIUs were ever infected) or Σ(exactly j AIUs out of n were infected and all j AIUs are now agent-free)].

$= \underline{(1 - p_1)^n + \Sigma\, (n!/j!(n-j)!)\, p_1^{\,j}\, (1-p_1)^{n-j}(1-p_2)^j}$

where $\underline{p_1}$ = probability that a single AIU is infected,
$\underline{1-p_2}$ = probability that the agent does not survive.

Then,
$P(O) = [1-[(1-p_1)^n + \Sigma(n!/j!(n-j)!)\, p_1^{\,j}(1-p_1)^{n-j}(1-p_2)^j]] * p_3 * p_4 * p_5 * p_6 * p_7 * p_8$

For the risk analysis process a computational expression is used to facilitate a transparent calculation of the risk and it does not necessitate the n iterations of the binomial theorem. As well, words are used instead of notation.

Risk Analysis process

1. Risk of unrestricted importation

The unrestricted risk estimate is an estimate of the risk associated with the importation of a commodity in its usual commercial form. It is referred to as "unrestricted" as it represents the risk before any risk reduction options are selected and applied. Quarantine, diagnostic testing, and further processing are such options. This risk estimate is a product of two probabilities, the probability of agent entry [P(I) as described above] and the probability of domestic exposure [(P(X|I) as described above (see Figure 2)].

a) Probability of Agent Entry

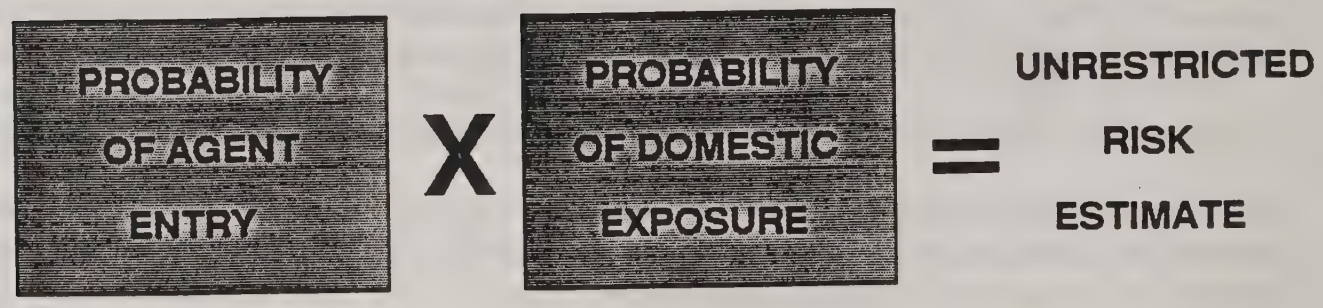
This is the probability that at least one animal import unit of the commodity importation is infected/contaminated with a disease agent. It is a product of two probabilities and is a function of the number of animal import units.

i) Country Factor. The country factor is an estimate of the prevalence of the disease in the exporting country (P(A) or p_1 as described above) based on the reported disease occurrence and an overall assessment of the veterinary services and disease situation. The prevalence is computed from the annual number of new outbreaks and the animal population statistics that are reported to the OIE and the average duration of infection of the disease. For OIE List B diseases, an assigned prevalence based on the range of prevalence found in the scientific literature is given to the OIE reported disease occurrence levels of exceptional, low sporadic, enzootic, or high. The three nondescript categories of disease occurrence, namely, suspected but not confirmed; serological evidence and/or isolation of causative agent, no clinical disease; and, disease exists, distribution and occurrence unknown, are assigned an exceptional prevalence. Information on the veterinary infrastructure, border control, disease situation in neighboring countries, regionalization of the disease, and import and disease control policies and practices are used to modify the prevalence estimate.

ii) Commodity Factor. The commodity factor is a probability estimate based on the presence/survivability of a disease agent in a commodity. This is P(B) or p_2 as described above. The species, age, and breed of animal influence the commodity factor of animal importation. For animal product or animal by-product importation the species of origin, the processing, and the handling dictate the probability level.

iii) Animal Import Units. The number of animal import units being imported obviously influences the probability of agent entry. Product quantities must be equated to animal import units. A standard set of equivalences for animal products can be established. One such set that overestimates the number of animal import units yet provides a measure for protection of the importing country is as follows:

Figure 2. Quantitative risk assessment model



Probability of agent entry =

$$1 - \left(1 - \text{COUNTRY FACTOR} \times \text{COMMODITY FACTOR}\right)^{**}$$

** NO. OF ANIMAL IMPORT UNITS

one animal import unit of the respective species equals 100 kg beef, 25 kg pork, 10 kg mutton or lamb, 10 kg goat meat, 100 kg horse meat, 1 kg poultry meat, 1 kg rabbit meat, 1 kg dairy products, 0.5 kg egg products, 20 kg cattle hides, and 5 kg sheep or goat hides. Equivalencies are needed for all animal products and not only product groups as indicated above.

b) Probability of Domestic Exposure

The probability of domestic exposure is the likelihood that the commodity will be exposed to animals or man of the importing country and agent transmission, infection, disease, disease spread, and disease detection occurs. The probability of domestic exposure is $P(X|I)$. Various scenarios exist that permit the exposure of the commodity to animals or man (see Table 1).

The probability of domestic exposure is estimated by the use of detailed scenario trees. The "as planned" scenario is the importation of the commodity for its intended use without the occurrence of an adverse event. Departures from this planned scenario are called initiating events or initiating failures. Each scenario is depicted diagrammatically as a path with one or more branch points. And each segment of a path has a frequency of occurrence called a split fraction. The frequency of each path is therefore a product of the initiating event frequency and all split fraction frequencies. Since these parameters are generally not known, probability density function curves are generated by processing all the evidence available with Bayes Theorem. The probability of a frequency is then the parameter assigned to each segment of the path (1).

Depending on the commodity, intended domestic use, the species affected, vector species and the demographics of animal and human populations, the number of initiating events will vary. One example of a scenario follows the initiating event of imported ham being infected with hog cholera virus with branch points including the feeding of ham scraps to swine.

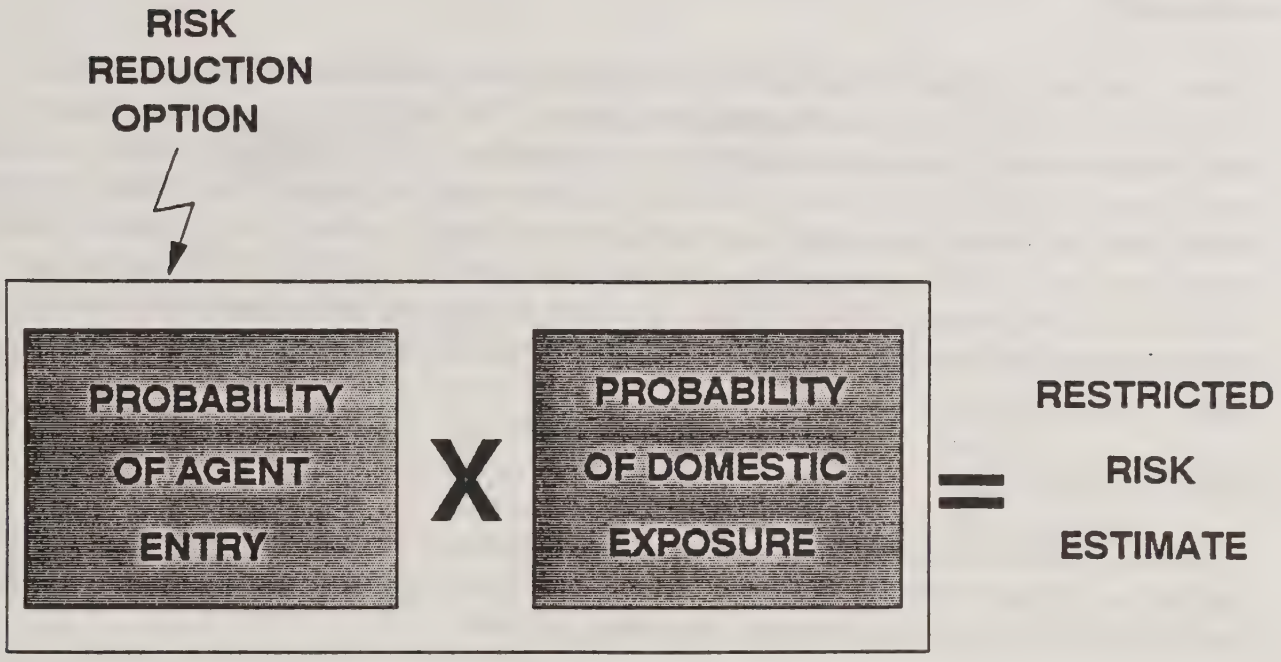
2. Risk of Restricted Importation

Many tools exist which can reduce the risk associated with commodity importation for an exporting country. These risk reduction options include heat treatments for specified times and temperatures, diagnostic testing, quarantine, quarantine with sentinel animals and certification of origin of the commodity. The restricted risk estimate is an estimate of the risk associated with the importation of a commodity that has been subjected to one or more risk reduction tools (see Figure 3). The latter act to reduce the probability of the commodity factor and/or the probability of domestic exposure. Hence, the restricted risk estimate is computed similarly to that of the unrestricted risk estimate.

Table 1. Some import commodity groups and associated modes of disease transmission and target species.

Commodity Group	Scenario	Target Species	Portal of Entry	Facilitates What Mode of Transmission	Disease Examples
Cattle	contact	domestic animals, man	various	direct, vector-borne	FMD, anaplasmosis, brucellosis
Bovine Semen	contact	cattle	reproductive	direct	FMD, leptospirosis
Bovine Embryos	contact	cattle	reproductive	direct	FMD
Beef	scraps fed	swine	gastro-intestinal	vehicle-borne	FMD, cysticerocosis
Beef	consumed	man	gastro-intestinal	vehicle-borne	echinococcosis
Swine	contact	domestic animals, man	various	direct, vector-borne	ASF, HC, Japanese encephalitis
Pork	scraps fed	swine	gastro-intestinal	vehicle-borne	SVD, trichinellosis
Pork	consumed	man	gastro-intestinal	vehicle-borne	trichinellosis
Sheep, Goats	contact	domestic animals, man	various	direct, vector-borne	scrapie, brucellosis
Lamb, Mutton, Chevron	scraps fed	swine	gastro-intestinal	vehicle-borne	echinococcosis
Horses	contact	domestic animals, man		direct, vector-borne	US, rabies, Japanese encephalitis
Horse Meat	scraps fed	swine	gastro-intestinal	vehicle-borne	trichinellosis
Horse Meat	consumed	man	gastro-intestinal	vehicle-borne	trichinellosis
Milk & Milk Products	fed	swine	gastro-intestinal	vehicle-borne	FMD, brucellosis, tuberculosis
Poultry, Birds	contact	poultry	various	direct, vector-borne	ND, fowl typhoid, fowl pox
Poultry, Birds	contact	man	various	direct	psittacosis
Cattle Hides	via man	cattle, sheep, goats, swine, man	gastro-intestinal	vehicle-borne	FMD, anthrax
Animal Feeds: Cattle blood & meat meals, horn and hoof meals, fats & oils	fed directly	cattle, sheep, goats, swine	gasto-intestinal	vehicle-borne	FMD, anthrax, BSE
Feather Meal	fed directly	poultry	gastro-intestinal	vehicle-borne	ND
Sheep Blood & Meat Meals	fed directly	cattle, sheep, goats, swine	gastro-intestinal	vehicle-borne	FMD, anthrax, BSE, scrapie
Milk Replacers	fed directly	cattle, sheep, goats, swine	gastro-intestinal	vehicle-borne	FMD

Figure 3. Quantitative risk assessment model and risk management



3. Decision-Making

Risk analysis includes risk assessment, management, and communication. From the request for importation to the generation of a quantitative risk assessment summary report and finally to announcement of the decision, a risk analysis process is followed (see Figure 4a and 4b). Decision-making is the process whereby the unrestricted risk estimates or the restricted risk estimates are assessed and the option to import is deemed as acceptable or not acceptable. In the case of high unrestricted risk estimates, risk reduction options may be selected. The risk of disease introduction that has public health significance or evokes strong public reaction can be highlighted in order that low probabilities of these are not overlooked.

A means to assist decision-making is to multiply the risk estimates by the economic consequences, the cost of the disease introduction. This includes the cost of disease eradication whether the disease is foreign or indigenous to the importing country, and for some diseases to include the losses from a one year trade embargo. Depending on the country and its disease situation, trade embargos primarily involve List A disease incursions. A one year trade embargo represents the minimum period and follows an immediate eradication. The value in United States currency for animal and animal product exports is obtained from the Food and Agriculture Organization of the United Nations Yearbook of Trade.

Reference

1. Kaplan, S. 1991. Quantitative Risk Assessment (QRA): A Tool for Management and Regulation. Presentation given to the U. S. Department of Agriculture Animal and Plant Health Inspection Service, Lanham, Maryland. 12 June.

Figure 4a. Import Risk Analysis System process

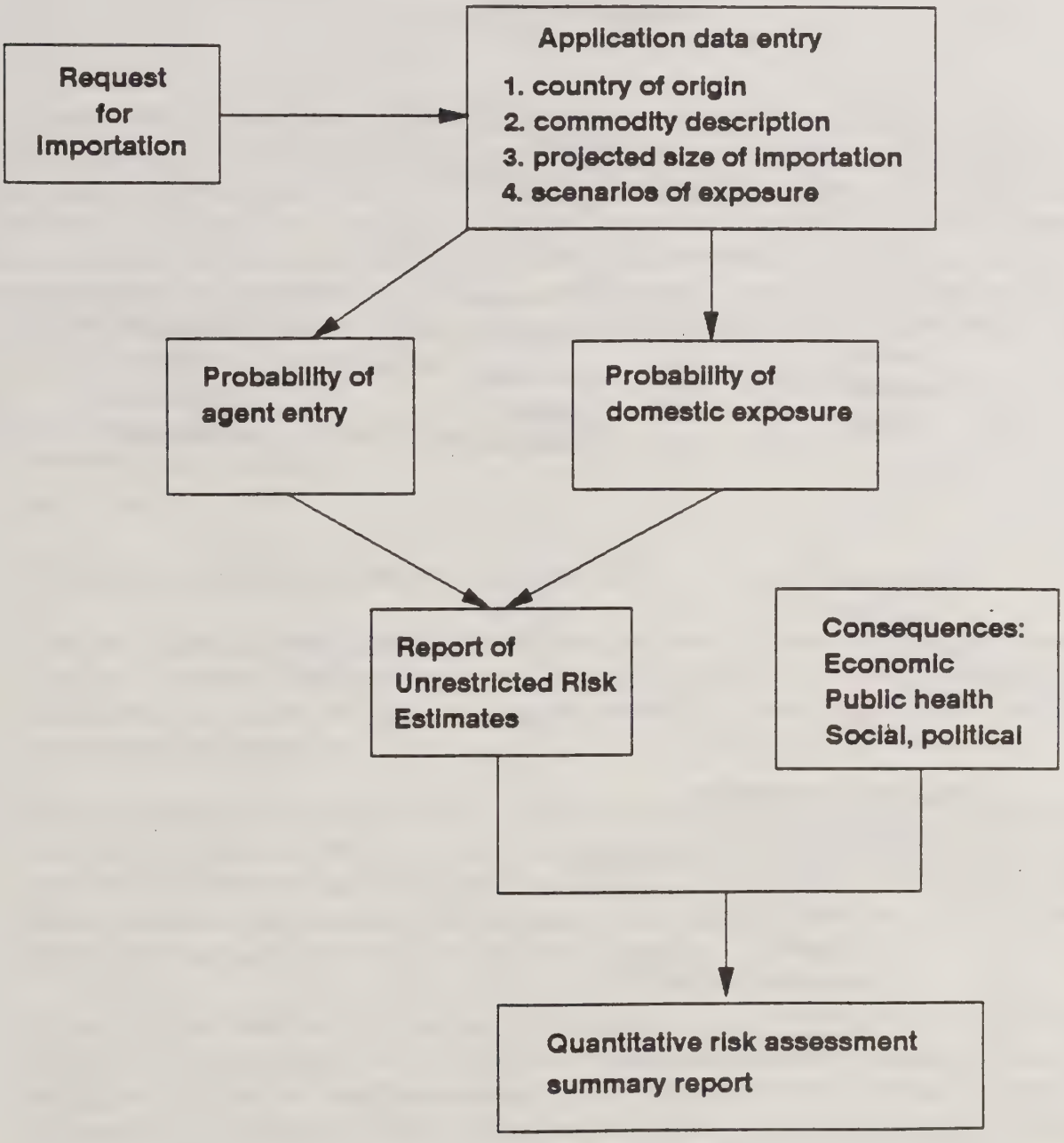
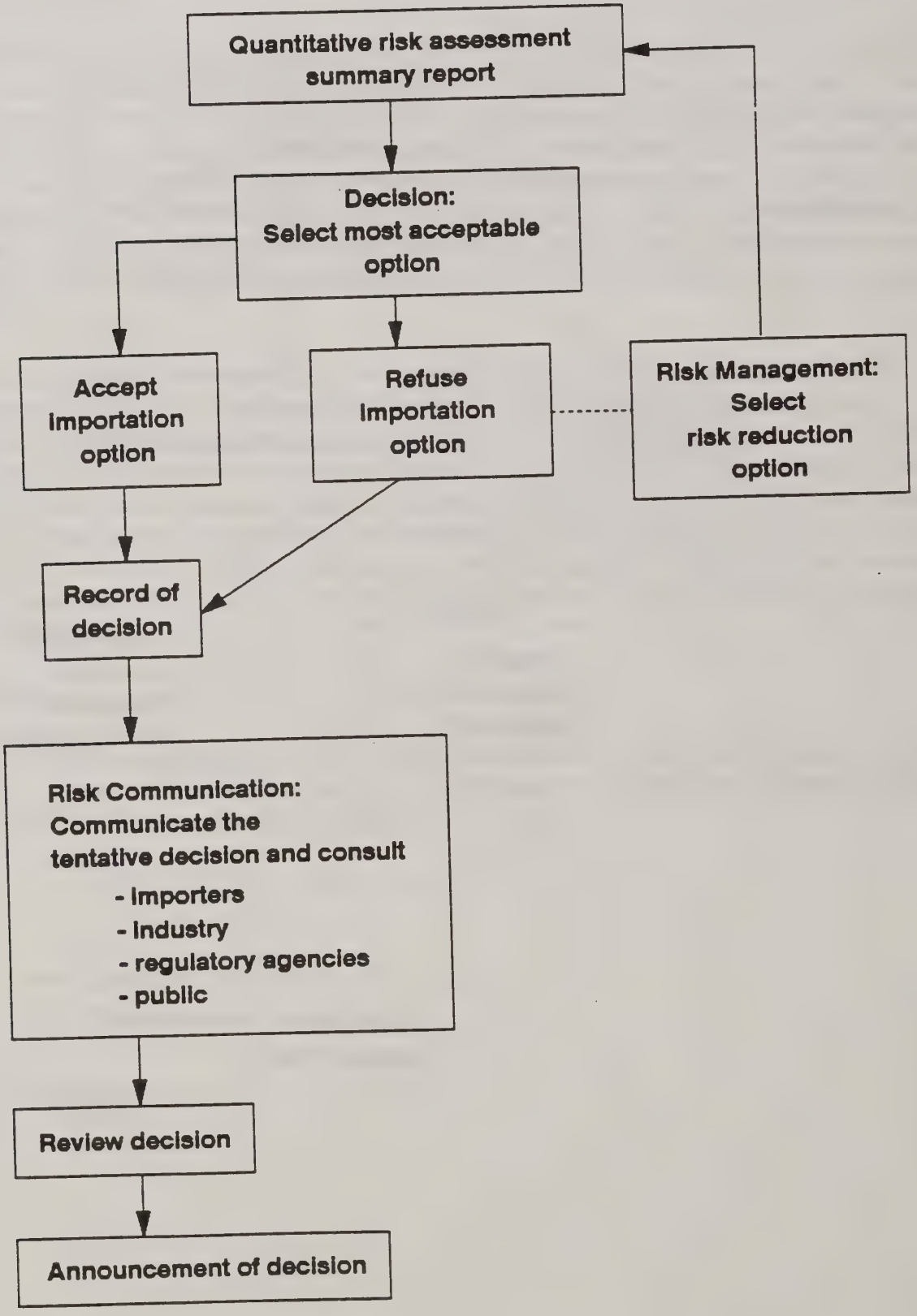


Figure 4b. Import Risk Analysis System process



THE INTERNATIONAL OFFICE OF EPIZOOTICS (OIE) ANIMAL DISEASE REPORTING SYSTEM

Thierry Chillaud

The Central Bureau of the International Office of Epizootics (Office Internation des Epizooties), hereafter referred to as OIE, is the focal point of an international animal disease reporting system which is made up of the animal disease information services of all OIE member countries. The input of data for the system is derived from animal disease information received from OIE member countries. This information on animal disease, depending on its type, is sent to the OIE by telex, facsimile transmission, telegram, and mail. The OIE classifies the information and produces different reports accordingly, which are then sent out to member countries.

Aims of the international animal disease reporting

The system has three aims:

1. Alerting countries threatened by an epizootic

The risk of an epizootic spreading from another country worries many governments and their farmers. Such an event could adversely affect the livestock industry of a co untry, and may cancel out the gains in productivity achieved after years of work and investment in this sector.

Diseases are spread in many ways. Some are insidious and the speed of transmission can be very rapid. If this is the case, the veterinary service in charge of protecting the health of the national herd may be unable to act effectively in the absence of al most immediate notification of an epizootic in an adjoining country, or in a country from which animals or animal products are imported.

Of course, the relevant information can be communicated directly from the affected country to the country at risk, and such a procedure should be encouraged, as it reinforces the mutual confidence which needs to be established between countries for matters concerning animal health. However, if this is the only procedure used, certain destinations may be overlooked due, for example, to communication problems, and it would be difficult to analyze information arriving from various sources over different periods of time. In addition, international coordination of me asures aimed at eradicating the epizootic would be impossible. It is therefore evident that the OIE plays an important role in centralizing processing and disseminating inf ormation on the geographical distribution and evolution of the major diseases of ani mals worldwide.

2. International cooperation

Thanks to the OIE's synthesis of the information it receives, it is possible to assess qualitatively and quantitatively (and not just intuitively) problems which may become important in a region or internationally. In the 1980's, for example, this system enabl ed the sudden increase in incidence of rinderpest in Africa to be brought under control by the rapid mobilization of international aid. The success of the Pan Africa n Rinderpest Campaign, created at this time, has been widespread and by 1989-1990 the disease occurrence had been reduced to a small number of outbreaks in certain East African countries.

3. Ease of international trade

Knowledge of the geographical distribution of the major diseases throughout the world and their evolution is essential, as it enables importing countries to protect the mselves by insisting that exporting countries apply the most appropriate preventative measures. In this respect, the existence of a veterinary service capable of providing constant surveillance of the health of the national herd and supplying the corresponding up-to-date information to the international community, is a prerequisite for every country which seeks to plan animal health and production programs and to encourage imports and exports of livestock and livestock products.

Presentation of the international animal disease reporting systems

1. Basic obligations of OIE member countries

In accordance with the International Animal Health Code, the national Veterinary Service of each OIE member country has agreed to communicate animal disease information to the OIE, adopting as closely as possible the reporting method described in the "Manual of Procedures for Immediate and Monthly Reporting of Sig nificant Disease Outbreaks to the OIE", as well as all other information which would help to clarify the status of the disease and the risks of its spread (Resolution No. VI II adopted by the OIE International Committee during the 55th General Session).

At the OIE, animal disease are classified into two lists, OIE Lists A and B (see Table 1).

List A comprises 15 highly contagious, notifiable animal diseases capable of crossing frontiers and thus becoming a threat to those countries either planning or already en gaged in international trade. They are either immediately reported to the OIE when they occur in a country or a zone regarded as free from the disease, or are detailed in the monthly report of the country concerned. OIE List B comprises 96

Table 1 - OIE LISTS A AND B DISEASES

LIST A DISEASES

Foot and mouth disease
Vesicular stomatitis
Swine vesicular disease
Rinderpest
Peste des petits ruminants
Contagious bovine pleuropneumonia
Lumpy skin disease
Rift Valley fever
Bluetongue
Sheep pox and goat pox
African horse sickness
African swine fever
Hog cholera
Fowl plague
Newcastle disease

LIST B DISEASES

Multiple species diseases

Anthrax
Aujeszky's disease
Echinococcosis/hydatidosis
Heartwater
Leptospirosis
Q fever
Rabies
Paratuberculosis
Screwworm (Cochliomyia hominivorax)

Cattle diseases

Anaplasmosis
Babesiosis
Bovine brucellosis (B. abortus)
Bovine genital campylobacteriosis
Bovine tuberculosis
Cysticercosis (C. bovis)
Dermatophilosis
Enzootic bovine leukosis
Haemorrhagic septicaemia
Infectious bovine rhinotracheitis (IBR/IPV)
Theileriosis
Trichomoniasis
Trypanosomiasis
Bovine malignant catarrh
Bovine spongiform encephalopathy (BSE)

LIST B DISEASES (contd)

Sheep and goat diseases

Brucella ovis infection
Caprine and ovine brucellosis (B. melitensis)
Caprine artritis encephalitis
contagious agalactia
Contagious caprine pleuropneumonia
Enzootic abortion of ewes
Pulmonary adenomatosis
Nairobi sheep disease
Salmonellosis (S. abortus ovis)
Scrapie
Maedi-Visna

Horse diseases

Contagious equine metritis
Dourine
Epizootic lymphangitis
Equine encephalomyelitis
Equine infectious anaemia
Equine influenza (virus type A)
Equine piroplasmosis
Equine rhinopneumonitis
Glanders
Horse pox
Infectious arteritis of horses
Japanese encephalitis
Horse mange
Salmonellosis (S. abortus equi)
Surra
Venezuelan equine encephalomyelitis

Pig diseases

Atrophic rhinitis
Cysticercosis (C. cellulosae)
Porcine brucellosis (B. suis)
Transmissible gastroenteritis of pigs
Trichinellosis
Enterovirus encephalomyelitis

Poultry diseases

Avian infectious bronchitis
Avian infectious laryngotracheitis
Avian tuberculosis
Duck virus hepatitis
Duck virus enteritis (duck plague)
Fowl cholera
Fowl pox
Fowl Typhoid (S. gallinarum)
Infectious bursal disease (Gumboro disease)

LIST B DISEASES (contd)

Marek's disease
Mycoplasmosis (M. gallisepticum
Psittacosis and ornithosis
Pullorum disease (S. pullorum)

Lagomorph diseases

Myxomatosis
Tularaemia
Viral haemorrhagic disease of rabbits

Fish diseases

Viral haemorrhagic septicaemia
Spring viremiasvirosis (Type 2)
Infectious haematopoietic necrosis
Salmonid herpesvirosis (Type 2)
Renibacteriosis (R. salmoninarum)
Ictalurid herpesvirosis (Type 1
Enzootic haematopoietic necrosis
Edwardsiellosis (E. ictaluri)

Mollusc diseases

Bonamiosis
Haplosporidiosis
Perkinsosis
Marteiliosis
Iridoviroses

Crustacean diseases

Baculovirosis (B. monodon)
Baculovirosis (B. penaei)
Baculoviral midgut gland necrosis
Infectious hypodermal and haemopoeitic necrosis

Bee diseases

Acariasis of bees
American foul brood
European foul brood
Nosematosis of bees
Varroasis

Diseases of other animal species

Leishmaniasis

diseases considered important to the national economy and which have significant effects on trade.

According to Article 1.2.0.3. of the OIE Code, Veterinary Administrations must notify the OIE by telegram, telex, or facsimile transmission within 24 hours of the following:

- for List A disease, the first occurrence or re-occurrence of the disease if the country or region of the country was previously considered to be free from the particular disease;

- for List A diseases, important new findings which are of epidemiological significance to other countries;

- for List A diseases, a provisional diagnosis of the disease if this represents important new information of epidemiological significance to other countries;

- for diseases which are not in List A, if there are new findings which are of epidemiological significance to other countries.

This notification is supplemented by a weekly report, sent by telegram, telex, or facsimile transmission, providing further information concerning diseases reported under the 24-hour rule.

Article 1.2.0.3. of the Code also stipulates that Veterinary Administrators submit:

- monthly reports on the absence or presence and evolution of diseases in List A, and findings of epidemiological importance to other countries with respect to diseases which are not in List A;

- annual reports on all diseases in Lists A and B and any other diseases considered to be of socio-economic importance or of major veterinary interest.

2. Animal Health Status Reports

Standard forms have been designed to improve the quality of international reports on animal diseases. The primary purpose of these forms is to assist other countries in reporting in a structured manner and facilitate computer storage of the information. Countries should make every effort to complete these forms and should all be able to supply, without any difficulty, the most important epidemiological indicators requested in the three forms used, namely S.R.-1, S.R.-2, and S.R.-3.

- S.R.-1; if the information is related to a List A disease not previously occurring or for which, if already present, there are important new findings, or if the information concerns exotic List B or other diseases that are of exceptional epidemiological importance to other countries, then notification of the OIE by telex, facsimile transmission, or telegram using the S.R.-1 form should take place within 24 hours.

- S.R.-2; in the same way, S.R.-2 forms should be used to send the follow-up information, the positive or negative developments of the disease. These forms should be sent by telex, facsimile transmission, or telegram.

- S.R.-3; as well as reporting such major developments, all member countries have to make routine reports to the OIE on the absence, presence, or evoluti on of List A diseases. As far as possible, this information should be given on a monthly basis using the S.R.-3 report form.

Animal statistics, animal health status, and disease control methods report

OIE member countries should pay great attention when preparing their annual reports on the Animal Health Status and Disease Control Methods and Animal Disease Statistics because these documents are submitted as a special item to the International Committee during the General Session in May. They should indicate, on a monthly basis, in the table entitled "List A Animal Disease Outbreaks - Statistics", the number of outbreaks observed. The Animal Health Status Report should comprise a written report and a completed copy of the joint Food and Agriculture Organization (FAO)/OIE/World Health Organization (WHO) questionnaire.

Dissemination of animal disease information

All the information received from the member countries whether by telex, facsimile transmission, or telegram, or in a monthly or annual report, constitutes the input phase of the OIE animal health information system. During the input phase, data is processed at the Central Bureau, thus allowing the preparation of various publications which are then sent out by the OIE to the 116 member countries and several international organizations with which the OIE has reciprocal cooperation agreements [FAO, WHO, European Economic Community (EEC), IICA]. Reports generated by the OIE from the animal disease information received vary according to the classification and status of the disease in the notifying country.

On receipt of emergency reports (S.R.-1), the OIE Information Service immediately issues communiques by telegram, telex, or facsimile transmission to countries directly threatened by the disease so that they can take the necessary preventive measures. Other countries are informed by the weekly publication entitled Disease Information.

To allow member countries to follow the world situation in relation to List A diseases, the OIE Central Bureau publishes the monthly Bulletin, presenting information extracted from S.R.-1, S.R.-2. and S.R.-3 forms and other reports relating to List A diseases submitted to the OIE during the previous month. Based on information received throughout the year on S.R.-1, S.R.-2 and S.R.-3 forms and in annual reports and statistics, the OIE publishes an annual review entitled World Animal Health, to provide countries with comprehensive information on the worldwide status regarding Lists A and B diseases.

The data received in the joint FAO/OIE/WHO questionnaires are alson used to produce part of the FAO/OIE/WHO publication Animal Health Yearbook, World Animal Health, and Animal Health Yearbook are unique and contain information of inestimable value to the Veterinary Services of countries wishing to engage in international trade in animals and animal products. All the afore mentioned publications constitute the output phase of the OIE animal health information system.

Areas where progress is still required

1. Disease-related problems

The principal obstacles to the adoption of a common language for information on dis eases of animals are the following:

- very often a distinction must be made between the infection and the disease;
- characterization and nomenclature of infectious agents is not always precise;
- procedures adopted for recognizing a country as free from a disease are gener ally defective.

2. Country-related problems

Problems relating to declarations that countries submit to the OIE are also of severa l types:

(1) It is not unusual to find inconsistencies between the different reports submitted to the OIE, for example between several annual reports. Co mputerization does not provide a solution to the problems encountered in interpreting certain national reports; these problems can only be res olved by maintaining a permanent dialogue with the countries concerne d.

(2) Under-declaration by individual countries is another serious problem which the OIE must address. This phenomenon can stem from a wide variety of causes.Firstly, countries have a natural tendency to show littl

e interest in diseases which they do not consider to exert a powerful brake on the maintenance or development of animal production, partic ularly if the species involved is considered to be of secondary importan ce or is not the subject of significant external trade. The case of pestilence of small ruminants (peste des petits ruminants) in sub-Sahar an Africa is illustrative of this point.

In many situations this is aggravated by a low level of technical and vet erinary infrastructure for animal production, a limited knowledge of epi demiology, and insufficient means for field or laboratory investigation. All these factors contribute to limiting the capacity of the Veterinary Services to collect the required animal health information.

Compartmentalization of the Veterinary Administration and animal he alth research establishments may also be the source of under- declarati on. The result is a discrepancy between the official reports received an d information which comes to light from a study of scientific documents.

Lastly, when the economic consequences of a declaration are clearly great, the officials concerned may be tempted to hide the facts, or delay bringing them to the attention of the international community. This phenomenon is rare, and in present times almost certain to fail, particularly due to the dynamism of the press, which is ever ready to give wide publicity to any news of a sensational nature.

(3) The reports which countries are currently asked to submit are insufficie ntly precise with regard to the description of the animal disease control measures in force. In particular, the coding used to this effect in the FAO/OIE/WHO questionnaire, valuable though it may be, is in many ways too perfunctory to allow the application and efficacy of the report ed measures to be judged.

This results in countries which are known to have Veterinary Services with widely differing capacities for action appearing very similar from a comparison of the information supplied by each of them in the questionnaire. This analysis of the difficulties preventing the "ideal" fun ctioning of the OIE animal disease reporting system is not aimed at bri nging the very existence of the system into question. The system has, in fact, been adopted by an ever increasing number of OIE member co untries, which, as the years go by, are making increasingly better use of it, and in particular of the warning system.

Present and future action of the OIE

Improvement of concepts used in animal health

In 1989, the OIE thoroughly examined surveillance techniques for rinderpest, to be applied in countries previously infected, in order to verify that a country is free from both the disease and the infection (i.e., that there is no virus circulating among susceptible animals) as a result of implementation of control measures.

Since July 1990, the OIE has been attacking a problem whose worldwide importance is well known, namely foot and mouth disease (FMD). This was in response to a lett er from the General Agreement on Tariffs and Trade (GATT) requesting the OIE to update and develop guidelines evaluating the appropriateness of import restrictions, with special focus on the concept of an acceptable level of zoosanitary risk. Three main aspects were identified as being essential to the assessment of risks associated with FMD in international trade in animals and animal products: epidemi ology, commodities, and assessment of Veterinary Services. Each of these aspects has already been developed in great depth. Although definitions are already given for "disease free country" and "infected country" in the section on the epidemiological aspect, the concepts of "regionalization" and "FMD-free zone" have not yet been included.

In parallel with this approach limited to a single disease, discussions have been taking place on the concept of risk assessment in general, particularly thanks to the impetus of countries in the Americas region. A considerable amount of work is currently being undertaken by the Veterinary Services of Canada, in cooperation wit h researchers from the United States of America to make proposals to the OIE on this vast subject as early as next year. Once these proposals have been accepted, the principal recommendations of the OIE on international trade in animals and animal products will need to be reviewed in light of the adopted general concepts on risk assessment, using an approach similar to that employed for foot and mouth disease.

It will also be necessary to re-examine the animal health data currently collected by the OIE, so as to determine which are vital to allow each country to assess the risks associated with its imports, to complete these data if necessary, and issue directives to OIE Member Countries on how to carry out risk assessment. From a technical poi nt of view, the OIE will no doubt have to upgrade its existing equipment so as to opt imize the transmission of animal health data to Member Countries, preferably using a computerized system. Lastly, the OIE will, in all probability, have to assume the difficult task of maintaining an up-to-date list of countries and territories free from the various diseases having a major impact on international trade.

Improvement of national animal disease reporting systems

As mentioned above, certain countries encounter considerable difficulties in operating a national system for animal health surveillance. Countries in greatest need of improvement are those with the most limited resources, even for conducting fundamental activities which would improve the health status of their livestock, but the necessity of which they are unable to justify in the absence of information. There is no easy way to break this vicious circle. It is necessary to make a general assessment of the situation and to adopt the most appropriate solutions.

Activities undertaken since 1988 have responded to this preoccupation. Recognizing the need to provide wide circulation of animal health information in Asia and Oceania in order to promote the development of livestock farming in these regions and to intensify intra-regional trade in animals and products of animal origin, the OIE and the Asian Developme nt Bank (ADB) decided to collaborate in organizing a seminar on the reporting of diseases of animals for the countries of this region; this was held in Manila (the Phillippines) in November 1988. The seminar resulted in significant proposals concerning the general organization and functioning patterns of effective national surveillance systems.

As a result of the seminar, a group of experts was designated to visit several countries, identify their common needs, and propose five types of national projects to meet these needs, which involve:

- development of decentralized systems for recording herd productivity and health;
- creation or improvement of systems for surveillance of the principal diseases;
- installation of regular circuits for information exchange (in which abattoirs and dairie s would participate) between owners of livestock and their advisers, and between cen tres for data processing and data analysis situated at the district, provincial, and national levels;
- development of diagnostic services;
- appropriate training of persons in the various categories involved in processing and evaluating the information obtained.

In 1990 the OIE commenced the third phase of its development aid action by organizing meetings of the level of each subregion in order to initiate subregional coordination projects between countries. A similar approach might be adopted for other regions, such as Africa and South America. However, the specific features of the organization, animal health situation, and available financial resources of each region will have to be taken into account before launching new programs aimed at responding to the needs of these regions.

Conclusion

The OIE plays an essential role in the prevention of animal diseases by providing information on animal diseases of economic importance to the international trade of

animals and animal products. Nevertheless, the success of the International Animal Disease Information System is based not only on the efforts of the OIE Headquarters; it is also heavily dependent on the availability and quality of information supplied by member countries, and therefore, on the existence of appropriate scientific capabilities, diagnostic services, and on adequate means of communication. The OIE thus intends to continue helping countries improve the quality of their surveillance systems, particularly through even greater international cooperation. The OIE will also do everything within its power to bring about harmonization of the different approaches which may be proposed for the assessment of animal health risks involved in international trade, since this is the only practical way to progressively lift all the unjustified barriers likely to hinder the development of international trade.

ENHANCING ANIMAL DISEASE SURVEILLANCE: EPI INFO AS A TOOL IN INTERNATIONAL ANIMAL DISEASE SURVEILLANCE

Peter J. Fernandez

"Animal health services throughout the world are making greater use of epidemiological methods in the management of animal health programs. These rely on the collection and analysis of much more field and laboratory data than was previously the case; hence, there is a need for organizing and interpreting epidemiological data to assist in decision-making." Jean Blancou

Animal disease data gathering and surveillance

The importance of gathering and analyzing reliable disease information is fast becoming a priority among nations involved in animal and animal product trade. Maintaining accurate animal health data is imperative for successful national control/eradication programs and also provides a means of assessment for trading partners of the extent of disease, if it is present. Risk analysis and regionalization will require accurate estimations of the animal disease situation in respective countries.

Epidemiology as a discipline tells us that valid disease inferences can only be drawn from unbiased information regarding the agent, the host, and their environment. Disease surveillance unites the spatial dimensions of disease with the important fourth dimension of time. A prerequisite to any surveillance program is a clear determination as to the purpose and use of gathered information. Surveillance of disease variables collected at individual farms or ranches should harmonize with macroepidemiologic surveillance at the national and possibly international level. Prompt collation, analysis, and interpretation of collected data should be considered a fundamental aspect of effective surveillance.

Two other important considerations for any disease surveillance program must be (a) what data variables are collected and (b) how should they be gathered. In order to maximize the value of databases at the international level, a standardization of variables and collection procedures must be established.

OIE's world animal disease information system

The International Office of Epizootics (OIE) has played a crucial role in sensitizing international animal health authorities to the importance of collecting and reporting animal diseases and in providing guidance in surveillance methodologies. As a response to the needs of national economies, the OIE has outlined three major purposes for an international system for reporting animal diseases: (a) to inform countries of disease spread, (b) to encourage multilevel international cooperation, and (c) to serve as a means of facilitating international trade. Additionally, the OIE acts as a resource of international

animal disease information producing monthly and yearly summary information. It is very likely that as the verification of disease status in individual countries acquires more importance with increased trade, the animal surveillance functions of the OIE will be pivotal.

According to Dr. Thierry Chillaud, Head of Information Systems for the OIE, the computerization of OIE animal disease reports began in 1982. The OIE Specialist Group on Animal Health Information Systems recommended the adoption of a micro-computer based system with flexible software capable of system expansion. The following year hardware and software specifications were agreed upon to meet both the technical and administrative needs of the OIE. By 1986 the OIE had a micro-computer system linked to a central unit and data processing software in place.

One of the major functions of the data-processor employed by the OIE, known as Multi-Log, is to aid in producing the invaluable monthly and yearly reports. Despite the system's ability to complete these tasks, recent advances in computer software have made the limitations of the data-processing system adopted by the OIE evident. For example, the database can only hold 60,000 records which would not maintain more than a projected one year of Status Reports-3 (S.R.-3) from member nations. Dr. Chillaud has calculated that under present hardware and software conditions, the addition of ten List A diseases would surpass current capacities to store monthly data.

Another disadvantage of the data-processing system is in the area of statistical analysis. The present OIE database can only do searches based on a unique variable based on country, disease, and date of outbreak. Multi-Log does not produce lists, frequencies, and cross tabulations, or perform any statistical analysis. Unfortunately, the system does not easily allow the transfer of information to other databases and statistical software packages which could serve as an adjunct. Dr. Chillaud informed me in August of this year that it is very likely that the OIE will begin using a more common database, such as dBase, in the near future.

These database system constraints, however, are minor when compared to the difficulties of obtaining accurate and timely reports from member countries. Reports sent to the OIE regarding monthly disease information often contradict yearly information submitted by the same country. There has also been some confusion on the part of member nations as to the definitions of variables collected, such as outbreak and case. The timeliness of reports has also hampered effective surveillance efforts by the OIE. According to Dr. Chillaud, reports can be late anywhere from 6 months to a year or longer in some instances.

In an article by Drs. L. Blajan and Chillaud regarding reporting, they state, "The regularity of notifications and the quality of data transmitted by countries are indispensable for the development of a truly sophisticated information tool by the OIE Central Bureau". The

authors subsequently indicate that future improvements of the OIE database are needed especially in the areas on database capacity, reader access by individual veterinary services, and telephone transmission of data to and from the OIE.

EPI INFO: A word processing, database, and statistics system

In April of this year (1991) I had the opportunity to meet with Dr. Chillaud in Paris in order to better understand the data collection techniques employed at the OIE and determine methods to more quickly access computer generated monthly information. I had been encouraged by Drs. Glosser and Thiermann to demonstrate to Dr. Chillaud some of the work I had been doing in international animal disease surveillance using EPI INFO software. After my meeting at the OIE, Dr. Blancou invited me to demonstrate EPI INFO to interested representatives at the 59th General Session of the OIE in May of this year.

EPI INFO is a group of microcomputer programs used to write a questionnaire format, enter data into that format, and perform basic analyses and graphs of the collected dataset. EPI INFO was designed by Andrew Dean, Jeffrey Dean, Anthony Burton, and Richard Dicker, of the Centers for Disease Control (CDC), U. S. Public Health Service. The main intent in creating this program was to allow local public health departments with limited funding, a computer program for the management and analysis of epidemiologic data. Versions 1, 2, and 3 of EPI INFO were completed at the CDC in the early 1980's. In 1988, the World Health Organizations (WHO) Surveillance, Forecasting and Impact Assessment Unit of the Global Program on AIDS modified and distributed EPI INFO version 4. The last version of EPI INFO, version 5, is the product of a collaborative effort by the CDC and the WHO. It is estimated that since 1987 over 4,000 copies of EPI INFO have been distributed in more than 34 countries.

I presently employ EPI INFO in collating OIE monthly data for facilitating the writing of summary reports such as the World Animal Disease Update in Animal and Plant Health Inspection Service's (APHIS) Foreign Animal Disease Report. Yearly prevalence information can also be entered into EPI INFO to generate lists for producing disease distribution maps. I have helped other co-workers at APHIS use EPI INFO for varied projects relating to plant interception worksheets and insect trapping surveillance. The actual entry of each disease report published in the monthly OIE Bulletin is very time consuming. The OIE had offered to send data on diskette, however, the format in which it was sent was not readily accessible by any common database program. This past summer we were successful in using various modules in EPI INFO to manipulate OIE data for record entry.

EPI INFO was purposely not copyright protected and the authors encouraged the copying of the disks and the manual. The program itself is very user friendly with all major functions operated with the up and down arrow and enter keys. The ANALYSIS and EPED (word processor) modules contain tutorials introducing their major features. EPI INFO has modules prepared specifically for importing data from common data formats such

as Lotus 1-2-3, dBase II/III/IV, and fixed length and comma delimited formats. The ANALYSIS module can also perform direct analyses of dBase files. In order to perform more advanced statistical analyses, EPI INFO has a utility for exporting data to various statistical packages such as SPSS, SAS, Lotus 1-2-3, EpiStat, dBase II/III/IV, Statpac, and Basic.

A key advantage of EPI INFO in international surveillance are the languages into which it is being translated. The two languages in which EPI INFO is presently available are English and French. A Spanish version has just been completed and is being tested. The Pan-American Health Organization (PAHO) has asked me to review this version for bugs and errors in the manual translation and we hope to see it available by the end of this year. While at CDC recently, a test copy of the Arabic version of EPI INFO to be distributed in 1992 was demonstrated. I was also informed that work has begun at the Shanghai Medical University's School of Public Health on a Chinese version of EPI INFO. These five languages are read or spoken by nearly 2 billion people. A program understood at this level would allow the interchange of varied information from animal health services from around the world. It would also promote the bridging of human and veterinary epidemiolo gy, especially in the area of analytical methodology.

The WHO and CDC are also developing a mapping program called EPI MAP to interface with EPI INFO. The mapping program will also be free to the public, however, this has made the acquisition of detailed cartographic information more difficult. At present, EPI MAP only contains general boundary files for some 60 countries and various regions. We hope to demonstrate some of the basic features of this mapping program later in the meeting.

After our demonstration in Paris in May, the OIE informed me that a great number of member countries had shown an interest in pursuing further applications of EPI INFO in animal disease surveillance. Since that time, Dr. Chillaud and myself have been attempting to determine where best EPI INFO would serve the OIE and its members.

We felt that due to the program's agility it would probably be best suited as a type of field software for data entry and transmission. What we have foreseen is that possibly EPI INFO could be used by veterinary services in member countries to enter monthly data into the respective Status Report format questionnaires. At a predetermined time this data would then be transferred to the OIE either by floppy disk or electronic telecommunications for processing. Countries would then have reader-access to the cumulative totals reported for their country and could correct final reports. Member nations would also have reader-access to cumulative monthly reports for all countries who have reported disease information. Reporting forms could be tailored to meet the needs of individual national disease control programs, while at the same time include standardized data variables needed by the OIE.

This very same system that I have described is presently being implemented by the CDC to collect reportable human disease information from state health departments in the United States. The system developed by the CDC uses EPI INFO as the software and is called the National Electronic Telecommunications Surveillance System (NETSS). All 50 states of the U.S. send weekly computerized reports of notifiable diseases in a specific EPI INFO questionnaire format. Data is transmitted to a CDC computer by using a commercial telecommunications network or communicating directly over telephone lines. When the program first began in 1986, the CDC made a commitment to all 50 state health departments to create EPI INFO report questionnaires that met each states' individual needs with the understanding that they would also collect certain variables of national interest.

Conclusion

In an article by A. McLeod and L. Tyler in the OIE's technical review on Epidemiological Information Systems entitled "Steps in the Implementation of a Micro-computer Approach to the Management of Animal Disease Information" various ideal software criteria are presented. Some of the outlined requirements include (a) data storage (from sero-surveys, laboratory submissions, disease reports, etc.); (b) ability to produce summary statistics of collected data for reports; (c) perform higher level statistical analysis than is required for summary reports to demonstrate trends and associations related to animal health; (d) trial study result storage and analysis; (e) mapping capabilities to graphically display disease distribution; (f) calculate economic parameters dealing with animal health issues (spread sheet); and (g) allow programming of simulation models. The authors' projected cost of these software needs are $5,500 U.S. and implementation would take over a year and a half. If bought from a distributor, the cost of EPI INFO with manual, is $35 U.S. I repeat, however, that this program is free and the authors would like satisfied users to share it with friends, co-workers, and colleagues.

It is very hard to conceive that a program which can meet all the above criteria, is written in various languages, and costs the price of diskettes and handbook copying fees, is available. EPI INFO is by no means a panacea for disease surveillance programs. Any disease surveillance program's effectiveness will depend on the regular, timely, and accurate collection of information. EPI INFO can give animal health programs at least a head start in getting on the right track.

I would just like to end by saying that my hope is that after a sound international animal disease database is established, other institutions involved in epidemiologic research will be able to use it as a basis for future investigations in veterinary health and productivity.

STANDARDIZATION OF NOMENCLATURE FOR RISK ANALYSIS STUDIES

Alwynelle S. Ahl

The process of risk analysis and the act of doing risk assessments are not new; they have been accomplished for many thousands of years using experts and best judgments. However, the formalized science and discipline of Risk Analysis and Risk Assessment are relatively new. They depend on sophisticated databases, information systems, and fast computers which only recently have become available. Because of the potential for these systems to help us pull vast amounts of information together in order to make decisions in a way that is transparent, consistent, and documentable, they have become the promise of tomorrow.

As in any new or emerging discipline, the words used to talk about any given concept or idea are often given different names. Sometimes the same word is given different meanings. At other times a word is defined in an imprecise way so that its meaning is quite ambiguous even to those who share its use every day. Thus is the origin babble.

As a goal of preventing babble, we plead for nomenclatural unity, in somewhat the same way that Dr. Thierry Chillaud and Dr. Peter Fernandez have argued for unanimity in other aspects of international risk assessment. To facilitate that, the Risk Analysis Section of USDA/APHIS/PPD has brought together some words that are commonly used in risk studies and prepared definitions for them based on suggestions from the literature and from colleagues.

A copy of these definitions follows. In order to give the best opportunity for sharing, would you please take time to review these definitions and compare them with your own country's usage of them. For each definition, please indicate that the definition is either (1) satisfactory as is; (2) satisfactory with changes; or (3) unsatisfactory. For categories 2 and 3, please make changes, suggestions, or re-write the definition. If there is a term missing which you wish to include, please write a suggested definition. Then send me your changes and comments for the responses.

If you send along your name and address, I will send you a set of the collected responses. If you prefer to respond anonymously, it would be helpful if you give the name of the country in which you reside when you make your response.

Please send all revisions, responses, and comments to:

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Thank you for your interest in arresting Babble.

Suggested definitions for risk analysis studies:

Risk Analysis-the process that includes risk assessment, risk management, and risk communication.

Risk assessment-the process of identifying a hazard and evaluating the risk of a specific hazard, either in absolute or relative terms. It includes estimates of uncertainty and is an objective, repeatable, scientific process. Quantitative risk assessment characterizes the risk in numerical representations.

Hazard-elements or events that pose potential harm; an adverse event or adverse outcome. In risk analysis, hazard is specified by describing what might go wrong and how that might happen.

Risk-the likelihood and magnitude (of the consequences) of occurrence of an adverse event; a measure of the probability of harm and the severity of the adverse effects. Objective measurement and scientific repeatability are hallmarks of risk. In risk studies, it is common to use "risk" synonymously with the likelihood (probability or frequency) of occurrence of a hazardous event.

Safety-the degree to which risks are judged acceptable; a subjective decision of the acceptability of risk. In the literature, it is generally used when discussing safety for human health. In a regulatory context for agriculture, managers make decisions about, for example, an importation based on their evaluation of the safety of the action for the national herd.

Risk management-the pragmatic decision-making process concerned with regulating the risk. As a decision process, it is involved in evaluating options to diminish or control present and predicted hazards to the biological and/or fiscal health of agricultural commodities. The decisions made may result in preventive or restorative actions. Risk managers make implicit judgements about the safety of particular courses of action.

Risk communication-open, two-way exchange of information and opinion about risk leading to better understanding and better risk management decisions. It is a tool to provide a forum for interchange with all concerned about the nature of hazards, the risk assessment and how the risks should be managed; a tool to assure unambiguous interchange of information among those affected by the outcome of risk assessment activities.

Negligible risk (also known as tolerable risk, no significant risk, de minimus risk)-a mutually agreed upon measure of risk so low that all parties agree to accept risks at or

below this level under most circumstances. For example, a risk of less than or equal to 1 in a million with 95% confidence that a hazard will cause damage is a common standard in health and environmental risk studies.

Risk reduction options or mitigation measures-any action oractions which reduces the risk of an agent to cause harm to domestic livestock; they may be applied to animals or animal commodities. Examples include quarantine, diagnostic testing, inspections, restricted use, processing, sentinel monitoring, etc.

Unrestricted risk estimate-the measure of risk to agriculture if a commodity were to be imported in its usual commercial form with no risk reduction options or mitigation measures applied.

Acceptable risk-a management decision about the permissibility of hazard; a decision made in the risk management process about the safety of a regulatory decision, the acceptability of a hazardous event. It is a subjective decision about issues around which there may be substantial disagreement. To say that a hazard is acceptable, admissable, allowable, or permissible appears to trivialize the concerns of a client community. For good risk communication to occur, it is best not to use the phrase "acceptable risk".

Area-either a geographic area with natural boundaries or an administratively determined area with sufficient regulatory and quarantine enforcement to prevent both natural and artificial spread of the pest or disease; a parcel of land with defined geographical or legal boundaries.

Region-an area of relative homogeneity for a particular set of characteristics. A region may comprise a country. It may be a defined area within a country, an area comprising several neighboring countries, or an area comprising portions of several neighboring countries.

Regionalization-the standards, including those for risk analysis, developed by one country for a foreign region with respect to a pest, organism, or agent for a given commodity to be imported into the country developing the standards.

Pest or Disease-Free-used historically to refer to a country, area or region which met a given set of criteria. The implication was that any live animal or animal commodity originating in this area or region presented no hazard to an importing country from a particular agent or organism. Scientifically, it is not possible to prove the absence of an agent. Thus the term disease-free really means that the agent, if it was present, occurred at an extremely low prevalence. This however, is not the same thing as absence. Thus, the risk associated with the importation of commodities from such an area would be negligible, tolerable, de minimus, presenting no significant risk.

Organism-any active, infective, propagative or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, viruses, viroids, or any entity characterized as living, related to any of these. It is an entity whose reproduction is based on nucleic acids.

Agent-a vector, organism, or chemical of concern which causes a disease or other hazard to an agricultural commodity or resource.

Vector-an organism which can carry and transmit disease.

Native-grown, produced, or originating in a particular area; inborn, natural, indigenous.

Exotic or foreign-situated outside an area; born in or belonging to, or characteristic of some other area. That which is not known to occur in a given area or region.

Pathway-any means and/or route by which an agent can move or be moved from one place to another.

Quarantine-enforced isolation or restriction of free movement of a commodity imposed to prevent an agent from spreading.

Commodity-an animal or animal product being considered for import.

Commodity factors-parameters peculiar to an animal or animal product (plant or plant product) which affects the likelihood that the unit, if contaminated, will carry, maintain, and transmit an agent after arrival in the country of destination.

Origin factors (Country factors)-parameters peculiar to a country that affect the likelihood that an agricultural commodity will be contaminated with a pest or agent; **e.g.** prevalence estimates, veterinary infrastructure, plant inspection procedures, border controls, disease control practices, etc.

Destination factors-parameter peculiar to the intended use of a commodity that affect the likelihood that the commodity, if contaminated, will expose appropriate host (animal or plant) populations.

Data-facts, information organized for analysis or used as the basis for a decision.

Database-a collection of data arranged for ease of use and speed of retrieval, as by a computer.

Information-knowledge derived from study, analysis, or experience; in computer science usage, data that can be coded for processing by a computer or similar device.

Information system-a system concerned with the gathering, manipulation, classification, storage and retrieval of data and information contained in databases; usually associated with the computer as the organizing element.

Geographic Information System (GIS)-computer-based systems for storing, retrieving, manipulating, analyzing, displaying and mapping data. It is used as a tool for planning, decision-making, and risk analysis.

THE NEED FOR ENSURING HEALTH IN THE INTERNATIONAL MOVEMENT OF ANIMALS

Jerry Callis

If someone has it, someone somewhere will want it, and our job in regulatory animal health is to make it safe to exchange it. If we do not, we can be assured it will move clandestinely anyway, and without health assurances to make it safe for U.S. animal agriculture. Though this has always been true, with the increasing volume of interchange between countries and with falling international barriers as in the European Economic Community, the need has grown too.

Increasingly, if you as a country want to export, you must be willing to import. Again, the world trade situation has changed so that the U.S. position in international trade is not one of dominance as in the past. If we shut out the rest of the world, they will not suffer, but we will.

In the past, the U. S. has had a NO RISK trading policy. Import policy has not asked "what is the risk?" Instead the policy has been simply to say "no". For example, the presence of arboviral disease transmitted by insects present in a cattle population has prevented the import of embryos from moving from one country to another. This despite the well-grounded research that shows that such an embryo import poses no risk to the cattle of the importing country. This kind of unnecessary exclusionary regulation cannot be sustained.

There are several reasons why exclusionary regulations can no longer be supported. First, "excessive regulatory action" is estimated to cost each U.S. citizen about $1,700 each year. Second, as the rest of the world works faithfully on a General Agreement of Tariff and Trade, we must genuinely join this effort or we will find others unwillingly to accept our animals and products. Third, it is foolish to maintain a system of exclusion just because it is a tradition. There must be just cause for decisions we make about importations.

One of the important things to remember is that enormous good has come to the livestock industries of various countries through animals imported into various countries. Canada, France, and the U.S. have all imported many cattle which have upgraded or led to genetic improvement of their local stocks. Of particular interest is the importation of Nelour cattle (Bos indicus) into Brazil and the value of these animals in the development of their industry. This story can be repeated for many other countries.

In the past, politics has been of first importance in import decisions, then economics second, with science as a distant third. It is time that regulatory researchers in science and economics make their finding known to the politicians so that the political deliberations will be well grounded in the natural and social sciences.

There is a growing need to ensure that animal health considerations are kept foremost in the international movement of animals.

ETHICAL AND MORAL CHALLENGES

John B. Kaneene

Introduction

Risk assessment and international trade in livestock and its products have attracted a lot of attention in the last five years. While risk assessment has traditionally been conducted in domestic disease control programs, the greatest challenge in this process has occurred when applied to international trade.

Veterinarians and scientists working for the government have often faced a delicate balance between providing factual risk assessment results and advising on international trade. This delicate balance has often evoked ethical and moral challenges. This paper is an attempt to clarify the role of the government veterinarian/scientist in this delicate balance between functions, risk assessment, and international policy advising.

Scientific objectives of this paper are to:

1) Briefly review the risk assessment process,
2) discuss who should be involved in the different areas of the risk assessment process, and
3) discuss ethical and moral challenges in risk assessment and policy advising tha t face governmental veterinarians/scientists in various countries.

Risk assessment process

The risk assessment process can be viewed as a three part process: 1) risk assessment, 2) risk management, and 3) risk communication. Risk assessment per se is the process of determining the risk (epidemiological and/or economic risk) of a hazard (infectious agent, chemical, or growth/production promoting compound) in a given animal/human population following exposure. Risk management, on the other hand, is the formulation and implementation of policy based on the results of the risk assessment exercise. Risk communication is the spreading of information regarding the size and nature of the risk, including government trading policies.

Who should be involved in the three parts of the risk assessment process?

The risk assessment exercise should be conducted by professionals/scientists without undue influence and/or pressure from politicians. This would produce unbiased results of the true risk, given the available data. Politicians should <u>not</u> be involved in this stage of the risk assessment process. Risk management (defined above) involves formulating and implementing policy. This stage should be conducted by the politicians based on the

unbiased risk information produced during the risk assessment exercise. During this stage, government veterinarians and/or scientists should be strictly informational. They should provide epidemiologic and economic risk information to the policymakers, but should not be used as policymakers.

The risk communication phase is a delicate one, and, to be effective, should occur at all levels. First, the veterinarians/scientists have a moral obligation to communicate the true risk to the policymakers, to the public within a given country, and to the international community. Second, the government policymakers have an ethical obligation to communica te the true risk to the public and the international community.

Risk assessment process and the public/consumer/industry in a given country

True Risk versus Perceived Risk

Throughout the whole risk assessment process, particularly as it relates to communication, it must be recognized that there is true risk and perceived risk. True risk is calculated based on available scientific data and appropriate methods. Perceived risk is formed by the public based on information from various popular media. It is important to remember that, in many cases, politicians tend to formulate policies in response to the media-driven perceived risk instead of using true risk information. Formulating policies based on perceived risk is quite dangerous. Usually such policies are very costly to implement and may lead to unnecessary unrest in a country or to trade wars between countries. One way to avoid such costly mistakes is to establish uniform methods and rules in such a way that policies relating to risk management can only be formulated and implemented following an adequate risk assessment exercise by professionals and scientists. A second way to avoid such costly mistakes is to establish well-defined channels of communication of true risk to the public by scientists and policymakers.

Epidemiologic risk versus economic risk

In a livestock risk assessment process, it must be remembered that two types of risk must be calculated--epidemiologic risk and economic risk. Epidemiologic risk assessment is the scientific determination of the probability of an agent (infectious agent, chemical, unwanted genetic trait, growth product) establishing itself in a given population of animals or humans and causing disease, reduced performance, and/or uncontrolled unwanted growth. Economic risk assessment is the determination of the economic impact that may result if infected and/or contaminated livestock and/or its products were to be introduced into a given population of animals and/or humans. Both epidemiologic and economic risk assessments need to be conducted, beginning with an epidemiologic one, if useful information is going to be generated.

Interest groups

In addressing the risk assessment of a given livestock enterprise, great caution needs to be taken in dealing with interest groups. Depending on whether a particular interest group is on the receiving or exporting end, the support and/or pressures will be different. It is best to conduct the risk assessment exercise phase (both epidemiologic and economic) without any influence from interest groups. After true risk rates have been established, the interest group can play a major role in communicating these risks to its various industries.

In the case of attempting to establish the risk of Bovine Spongiform Encephalopathy (BSE) being introduced into cattle populations in the United States, committees have been formed to determine the true risk. Following their report, interested livestock industries, feed manufacturers, and rendering plant companies have communicated the risk to their industries and have participated in an established surveillance program.

Risk assessment process and international trade

Risk assessment and trade between developed countries

Many developed countries have surpluses in some livestock products and, because of this, special interest groups have put pressure on the government to restrict importation of similar products. In such circumstances, governments sometimes formulate policies based on perceived risk as opposed to real risk. Veterinarians and scientists have both ethical and moral obligations to communicate to policymakers what the true risk is.

One critical point in international trade is the standardization of risk assessment exercises and terminology. It is imperative that these two aspects be standardized so that risk communication between countries interested in bilateral trade can be effective.

Risk assessment and trade between developed and developing countries

Developing countries wanting to export livestock and/or livestock products must meet very strict standards. This is justifiable because developed countries do not want to risk their livestock. Developed countries, however, have ethical and moral obligations to use the same standards when exporting livestock and/or livestock products to developing countries.

Summary

1. Risk assessment should be functionally separated from risk management (policy).
2. Professionals/scientists should not be involved in policy/political issues, except to provide unbiased, scientifically sound information of the true risk.
3. Identical standards in the risk assessment process should be used between countries, regardless of their level of development.

4. Professionals/scientists have ethical and moral obligations in the whole risk assessment process.

Conclusion

The OIE plays an essential role in the prevention of animal diseases by providing information on animal diseases of economic importance to the international trade of animals and animal products.

Nevertheless, the success of the International Animal Disease Information System is based not only on the efforts of the OIE Headquarters; it is also heavily dependent on the availability and quality of information supplied by member countries, and therefore on the existence of appropriate scientific capabilities, diagnostic services, and on adequate means of communication.

The OIE thus intends to continue helping countries improve the quality of their surveillance systems, particularly through even greater international cooperation. The OIE will also do everything within its power to bring about harmonization of the different approaches which may be proposed for the assessment of animal health risks involved in international trade, since this is the only practical way to progressively lift all the unjustified barriers likely to hinder the development of international trade.